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 (CMS-9123-P)
Proposed Rule Summary

On December 14, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a proposed rule imposing new requirements on Medicaid and the state Children's Health Insurance Program (CHIP) fee-for-service programs, Medicaid managed care plans, CHIP managed care entities, and qualified health plans (QHPs) in the federally-facilitated exchanges (FFEs). Medicare Advantage organizations are not affected by this rule. The proposals aim to improve the electronic exchange of health care data and streamline prior authorization by building on previously adopted requirements pertaining to Application Programming Interfaces (APIs). Also in this rule, the Office of the National Coordinator for Health Information Technology (ONC) of the Department of Health and Human Services (HHS) proposes adoption of specific implementation guides needed to support the CMS policies proposed in this rule. Numerous requests for information are included. The proposed rule is scheduled to be published in the *Federal Register* on December 17, 2020. **The public comment period closes on January 4, 2021.**

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I. Background

This proposed rule builds on provisions of the Interoperability and Patient Access final rule[1] issued on May 1, 2020 (Patient Access final rule), under which CMS required affected payers to

[1] "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, state Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges and Health Care Providers" (85 FR 25510).

build and maintain APIs in order to increase patient access and data exchange and improve interoperability in health care. The API must conform with Health Level Seven International® (HL7) Fast Healthcare Interoperability Resources® (FHIR) and meet other specifications. Payers subject to this proposed rule are issuers of QHPs in FFEs, Medicaid and CHIP fee-for-service (FFS) programs, Medicaid managed care plans, and CHIP managed care entities. For purposes of this summary, the term "impacted payer" refers to this group. QHPs in FFEs exclude stand-alone dental plans and issuers only offering QHPs in the federally-facilitated Small Business Health Options Program Exchange are not subject to this proposed rule. FFEs include Exchanges in states that perform plan management functions; state-based Exchanges on the Federal Platform are not FFEs.

Affected payers in the Patient Access final rule also included Medicare Advantage (MA) organizations, but they would not be subject to the proposed requirements in this rule. CMS will evaluate whether to do so in future rulemaking. In the meantime, CMS observes that nothing in the Patient Access final rule or this rule precludes any payer from implementing the policies in this proposed rule regardless of whether they are directly impacted by it.

As explained by CMS, state Medicaid and CHIP programs were excluded from the payer-to-payer data exchange policies in the Patient Access rule so that these programs could focus resources on implementing the patient access and provider directory APIs required in that rule. It sees this proposed rule as a next step to require these FFS programs to exchange patient health information in a more efficient and interoperable way.

CMS believes the policies in this proposed rule that allow patients to retain their health information in electronic form and move with them among payers and providers will particularly benefit Medicaid, CHIP and QHP enrollees. "Churn," or movement of enrollees among these payers and in and out of health coverage, is common as individual and family circumstances affect eligibility status.

Terms used in the proposed rule are clarified. "Patient" is used throughout as an inclusive term although historically in some programs CMS has referred instead to "consumer," "beneficiary," "enrollee," or "individual." The term patient includes a patient's personal representative,[2] and could address policies in the proposed rule that require action by a patient. "Items and services" do not include prescription drugs or covered outpatient drugs.

The Patient Access final rule adopted nearly identical regulatory language for each affected payer. The sections of 42 CFR that are involved both in that final rule and this proposed rule with respect to Patient Access APIs are those for state Medicaid fee-for-service programs (§431.60); Medicaid managed care plans (§438.242(b)); CHIP fee-for-service programs (§457.730); and CHIP managed care plans (§457.1233(d)). In addition, 45 CFR 156.221 is modified, which pertains to QHPs in FFEs. The technical standards for APIs are set forth in 45 CFR 170.215; these would also be amended in this proposed rule. The Patient Access API regulations for FFS Medicaid and CHIP and QHP issuers in the FFEs have an identical structure

[2] Defined in 45 CFR 164.502(g) and discussed in Office of Civil Rights guidance at https://www.hhs.gov/hipaa/for-professionals/faq/2069/under-hipaa-when-can-a-family-member/index.html

of subsections, which are amended in this proposed rule. The regulations are generally applied to Medicaid and CHIP managed care plans through cross references.

II. Provisions of the Proposed Rule

Unless otherwise stated, the proposed new requirements would be effective January 1, 2023; for Medicaid and CHIP managed care plans and entities the requirements would be effective for the rating period beginning on or after that date.

A. Patient Access API

The Patient Access final rule requires that affected payers permit third-party applications to retrieve certain data through a FHIR-based API at the direction of a current enrollee. At a minimum, the payers must make available adjudicated claims (including provider remittances and enrollee cost-sharing); encounters with capitated providers; and clinical data, including laboratory results when maintained by the payer. Clinical data must comply with the US Core for Data Interoperability (USCDI) version 1 content and vocabulary standards. Data must be made available no later than one business day after a claim is adjudicated or encounter data are received. Affected payers must make available through the Patient Access API the specified data they maintain with a date of service on or after January 1, 2016.

1. Conformance to Implementation Guidance

In this rule, CMS proposes to require that Medicaid and CHIP programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs must assure that their APIs are in conformance with certain API Implementation Guidance[3] (IGs) to support interoperability. The IGs were discussed in the Patient Access final rule as useful to affected payers in meeting the requirements for the Patient Access API. Links to more information are provided on the CMS website for the Patient Access final rule. https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.

Under the proposal, impacted payers would have the choice to conform to either the US Core IG or the HL7 FHIR Da Vinci Payer Data Exchange (PDex) IG to facilitate making available the required clinical data via the Patient Access API. CMS had originally suggested the US Core IG but it has learned that some payers prefer the PDex IG because it offers additional resources for payer-specific use cases, and interoperability is ensured regardless of which IG is used. **CMS specifically seeks comments on the pros and cons of allowing the use of either of these IGs or whether only one IG should be required and why.**

CMS believes that continuing to allow optional adherence to the IGs could result in misalignment that prevents interoperability between providers and payers. In addition, the decision to propose mandating these IGs is in response to the Supreme Court decision in *Azar v.*

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

Allina Health Services 139 S.Ct.1804 (2019) which held that CMS must undertake notice and comment rulemaking for any statement of policy that changes a "substantive legal standard;" IGs are considered as such under that decision.

Recognizing the need to account for evolving IGs that would outpace its ability to update regulatory text, CMS proposes to allow regulated entities to use an updated version of any of the IGs proposed for adoption if the updated IG does not disrupt an end user's ability to access data through any of the specified APIs discussed in this proposed rule.

CMS notes that the IGs are publicly available at no cost to the user. All HL7 FHIR IGs are developed through an industry-led, consensus-based public process. HL7 is a standards development organization, and the IGs are open source which allows any interested party to access the IGs, where all public comments and a history of versions is available.

The proposed regulatory text reflecting this proposal regarding conformance with certain IGs appears in a new subsection (c)(3)(iii) and the proposal allowing updated IGs appears in a new subsection (c)(4) to the regulations for the following impacted payers: Medicaid fee-for-service programs (42 CFR 431.60); CHIP fee-for-service programs (42 CFR 457.730); and QHP issuers in FFEs (45 CFR 156.221). Through cross references, the proposed regulations would also apply to Medicaid managed care plans and CHIP managed care entities.

2. Access to Prior Authorization Information via APIs

CMS proposes to require that certain information regarding prior authorization be available to patients via the Patient Access API, which it believes will help ensure better patient understanding of the process. (CMS also proposes to make this information available through the Provider Access API, discussed in section II.B.3, and the Payer-to-Payer API proposed in section II.D). Elsewhere in this proposed rule CMS proposes changes to prior authorization processes for some payers (section II.C below).

Specifically, the proposed rule would require that impacted payers make information available to patients about any pending and active prior authorization decisions (and related clinical documentation and forms) for items and services via the Patient Access API no later than one business day after a provider initiates a prior authorization request or there is a change of status in the prior authorization. Pending prior authorizations are those that are under review, awaiting submission of documentation from the provider, being evaluated by the payer's medical review staff or for another reason have not yet had a determination made. CMS excludes denied or expired prior authorization decisions from the proposed requirement because including them could result in a significant amount of information that may no longer be clinically relevant at the time of the data exchange. It notes, however, that if the status of a pending prior authorization is changed to "denied" it would be shared through the API as a change in status.

CMS believes that making this information available to patients through the API will help patients understand which items and services require prior authorization, the information being considered to determine its outcome, and the "lifecycle" of a prior authorization request. Patients could follow the process and potentially help their provider produce necessary documentation

when needed. This might decrease the need for patients to make multiple calls to their provider. CMS also sees value in payers sharing information on pending and active prior authorization decisions with providers and other payers. Allowing a provider and new payers to see prior authorizations from other providers and payers may improve care coordination.

Comments are sought for possible future consideration on whether or not impacted payers should be required to include information about prior authorization decisions regarding prescription drugs or covered outpatient drugs via the Patient Access API, the Provider Access API, or the Payer-to-Payer API. CMS sees value to payers, providers, and patients from having information about a patient's prescription drug prior authorization decisions and would like to better understand and consider how to include this information most efficiently and effectively in these API provisions in the future. In particular, CMS asks for any specific considerations it should take into account and whether there are unique considerations related to the role Pharmacy Benefit Managers play in this process.

This proposal to make prior authorization information available through the Patient Access API appears in proposed regulatory text in a new subsection (b)(5) to the regulations for the following impacted payers: Medicaid fee-for-service programs (42 CFR 431.60); CHIP fee-for-service programs (42 CFR 457.730); and QHP issuers in FFEs (45 CFR 156.221) and applied to Medicaid managed care plans and CHIP managed care entities through cross references.

3. Privacy Policy Attestation

Under the proposed rule, impacted payers would be required to request a privacy policy attestation from third party application developers when their application requests to connect to the payer's Patient Access API. (The Patient Access final rule encouraged, but did not require, affected payers to request a privacy policy attestation from third-party application developers.) Specifically, CMS proposes that impacted payers be required to establish, implement, and maintain a process for requesting a privacy policy attestation from a third-party application developer requesting to retrieve data via the Patient Access API. The attestation would indicate that the application adheres to certain privacy provisions.

At a minimum, the required attestation would have to include whether:

- The application has a privacy policy that is publicly available and accessible at all times, including updated versions, is written in plain language, and the third-party application developer has affirmatively shared this privacy policy with the patient prior to the patient authorizing the application to access their health information. To "affirmatively share" means that the patient had to take an action to indicate they saw the privacy policy, such as click or check a box or boxes.
- The application's privacy policy includes, at a minimum, the following important information:
    - How a patient's health information may be accessed, exchanged, or used by any person or other entity, including whether the patient's health information may be shared or sold at any time;
    - A requirement for express consent from a patient before the patient's health information is accessed, exchanged, or used, including receiving express consent

before a patient's health information is shared or sold (other than disclosures required by law or disclosures necessary in connection with the sale of the application or a similar transaction);
- If an application will access any other information from a patient's device; and
- How a patient can discontinue application access to their data and what the application's policy and process is for disposing of a patient's data once the patient has withdrawn consent.

CMS notes that there are many ways a payer could meet this requirement, and it wants to avoid being overly prescriptive and to allow the market to develop innovative solutions. A payer could work with a third party for the attestation or could develop its own process and procedures. However, a payer may not discriminate in implementing this requirement for competitive advantage or other reasons. The method chosen must apply equitably across all applications requesting access to the payer's Patient Access API. CMS suggests that payers look to industry best practices, including the CARIN Alliance's Code of Conduct and the ONC Model Privacy Notice for content.

Impacted payers would be required to request the attestation from the application developer at the time the application engages the API. The payer would have to inform the patient within 24 hours of requesting the attestation as to its status – positive, negative, or no response, with an explanation of what each means. In the case where the payer receives a negative response or no response it may inform the patient of risks associated with sharing health information with the application. However, if the patient does not respond or chooses to proceed the payer must make the data available via the API. **CMS is interested in comments from the public on the payer's obligation to send the data regardless of whether the patient responds to the notification of the application's attestation results, particularly if the application does not attest to meeting the privacy provisions.**

Under the Patient Access final rule, affected payers must provide certain beneficiary resources regarding privacy and security; CMS proposes to modify that requirement for impacted payers to include information about the required privacy policy attestation for API data exchange. At a minimum, the information would include the timeline for the attestation process, the method for informing the beneficiary about the application developer's response, and the beneficiary's role and rights in the process.

CMS requests comments on additional content requirements for the privacy policy attestation and enrollee resources. It is particularly interested in hearing feedback on how best to engage available industry-led initiatives, as well as the level of flexibility payers think is appropriate for defining the process for requesting, obtaining, and informing patients about the attestation. For instance, CMS asks whether payers would prefer that CMS specify the types of communication methods payers can use to inform patients about the attestation result, such as via e-mail or text or other electronic communication only. It also asks how it should account for third-party solutions that present a list of applications that have already attested. Comments are sought on whether the application developer should be required to attest to each provision independently, (i.e., a line-item versus all-or-nothing approach to attestation); this would also

apply to the payer communication with the patient about the attestation. CMS seeks to understand the value to patients of these two alternatives.
The privacy policy proposal would be codified in a new subsection (g) to the regulations for Medicaid fee-for-service programs (42 CFR 431.60) and CHIP fee-for-service programs (42 CFR 457.730) and applied to Medicaid managed care plans and CHIP managed care entities through cross references. For QHP issuers in FFEs the policy would be found at a new 45 CFR 156.221(h).

4. Patient Access API Metrics

CMS proposes that impacted payers report metrics to CMS on patient use of the Patient Access API. Beginning on March 31, 2023, impacted payers would make quarterly reports on (1) the total number of unique patients whose data are transferred via the Patient Access API to a patient-designated third-party application and (2) the number of unique patients whose data are transferred via the Patient Access API to a patient-designated third-party application more than once. The data reported would be for the previous quarter, so that, for example, the initial quarterly report on March 31, 2023 would be on the data for October through December of 2022.

This proposal is made because CMS believes the information is necessary for it to understand whether the Patient Access API requirement is efficiently and effectively ensuring that patients have the required information timely and that it is being provided in a transparent way. CMS does not intend to publicly report these data at this time but may reference or publish them at an aggregate de-identified level.

CMS seeks comments on several issues related to the required reporting of API metrics:

- Whether it should consider requiring that these data be reported to CMS at the contract level for those payers with multiple plans under a single contract or whether to permit impacted payers to aggregate data for the same plan type;
- The relative burden associated with quarterly versus annual reporting;
- What other metrics CMS might require payers to share with it and potentially the public; and
- The burden if payers were required to report the names of the unique applications that access the payer's API. CMS is considering collecting this information to help identify the number of applications being developed, potentially review for best practices, and evaluate consumer ease of use.

The proposal for reporting of Patient Access API metrics would be codified in a new subsection (h) to the regulations for Medicaid fee-for-service programs (42 CFR 431.60) and CHIP fee-for-service programs (42 CFR 457.730) and applied to Medicaid managed care plans and CHIP managed care entities through cross references. For QHP issuers in FFEs the policy would be found at a new 45 CFR 156.221(i).

5. Technical Changes to Regulatory Text

Two changes are proposed for the Patient Access API regulatory text applicable to each of the impacted payers. First, 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. (See subsection (b)(3) at §431.60 for Medicaid FFS programs and §457.730 for CHIP FFS programs, and 45 CFR 156.221(b)(1)(iii) for QHP issuers of the FFEs.) Second, in the text addressing denial or discontinuation of access to the API, the term "parties" would replace "enrollees" and "beneficiaries." CMS believes this would be more accurate given that under provisions of this proposed rule other parties may be accessing the APIs, such as providers and payers. (See subsection (e)(2) at §431.60 for Medicaid FFS programs, §457.730 for CHIP FFS programs, and 45 CFR 156.221 for QHP issuers of the FFEs.)

6. Updates to Medicare Blue Button 2.0

While the proposals in this rule do not directly impact the Medicare fee-for-service program, CMS says that it is "targeting to implement the provisions, if finalized." Blue Button 2.0 makes claims data for Medicare Parts A, B and D available via an API to Medicare beneficiaries. CMS is updating the Blue Button 2.0 API to FHIR R4 and will begin use of the CARIN IG for the Blue Button. It says if the proposals in this rule are finalized it will work to align the Blue Button accordingly.

7. Provider Directory API Implementation Guide

Under the Patient Access final rule, affected payers must provide a Provider Directory API that makes provider names, addresses, phone numbers and specialties available to third-party applications. Providers have 30 days after receiving directory information or an update to provide the new or revised information. QHP issuers were made exempt from this requirement because they already had to make provider directory information available in a specified, machine-readable format.

CMS proposes that the Provider Directory API be conformant with a specified IG. Specifically, the proposed rule would require that the Provider Directory API conform to the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0. This change would appear in regulatory text at a new subsection (d) to the regulations for Medicaid fee-for-service programs (42 CFR 431.70) and CHIP fee-for-service programs (42 CFR 457.760) and at §438.242(b)(6) for Medicaid managed care plans and §457.1233(d)(3) for CHIP managed care entities.

8. Discussion of Statutory Authorities

CMS reviews the rationale for the proposals made regarding the Patient Access API and the underlying statutory authority for each of the impacted payer types.

B. Provider Access APIs

CMS proposes to require payers to implement and maintain a publicly accessible, standards-based Provider Access API to support data transfer from payers to providers. It notes that impacted payers will have prepared the necessary infrastructure to support the Patient Access API required under the Patient Access final rule. 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.

CMS believes that if providers have direct access to patient data it would benefit both providers and patients. For example, if providers have access to patient data it might improve the provider's understanding of the patient's health and improve the efficiency and effectiveness of patient care. It may also reduce the burden on patients to recall certain information during an appointment and patients may also be spared having to repeatedly fill out medical history forms.

The specific transactions for which Health Insurance Portability and Accountability Act (HIPAA) standards for electronic exchange of information have been adopted are listed; CMS states that the use of a HIPAA transaction standard is not required for its proposals regarding Provider Access APIs. The rationale offered for this conclusion is that the Secretary has not adopted a HIPAA transaction applicable to communications of claims or encounter information for a purpose other than requesting payment. The Provider Access API proposals do not involve data sharing for the purpose of making or obtaining payment.

The implications of the privacy rules required by HIPAA and specified at 45 CFR 164.502 for the Provider Access API are also discussed. Providers and other covered entities are responsible for using and disclosing data under HIPAA rules. The HIPAA Privacy Rule generally permits covered entities to use and disclose personal health information without the patient's authorization for facilitating treatment and coordination of care. However, CMS notes that payers and providers must still comply with all federal, state, local and tribal laws regarding privacy. In some cases, for example the regulations addressing substance use disorder data (at 42 CFR part 2), payers and providers may need to obtain patient consent to request or disclose behavioral health, certain substance use disorder treatment, or other sensitive health-related information, or they may have to use specified transactions to carry out certain defined data transfers between certain parties for specific purposes.

CMS would not allow payers to deny use of the Provider Access API based on whether the provider has a contract with the payer. It believes that providers should have access to their patients' data regardless of their relationship with the payer. However, a non-network provider would have to demonstrate that they have a care relationship with the patient.

1. General Approach

Under the proposal, impacted payers would be required to make available to a provider upon request and if permitted by the patient, the same data that is available to patients through the Patient Access API: claims and encounter data, clinical data as defined in USCDI Version 1, and formulary or preferred drug list data, where applicable for data maintained by the payer with a service date on or after January 1, 2016. As described elsewhere, under this proposed rule, availability of data on pending and active prior authorization decisions would also be required. Unlike the Patient Access API, however, the Provider Access API would not include remittances and beneficiary cost-sharing information. Another difference is that CMS anticipates the provider would receive the data for incorporation into its electronic health record or other practice management system as opposed to the mobile device application used by patients. As

mentioned above, 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.

Two approaches to the Provider Access API are proposed. One approach would allow providers to have access to an individual patient's information and would be generally parallel to the Patient Access API. The other, a bulk data approach discussed immediately below, would allow providers to access data on multiple patients at the same time.

Medicaid managed care plans that are Non-Emergency Medical Transportation (NEMT) Prepaid Ambulatory Health Plans would be exempt from the requirement to establish a Provider Access API. CMS states that the unique nature and limited scope of the services these plans provide is not consistent with the purposes of the Provider Access API. That is, CMS does not believe that providers have a routine need for NEMT data. (These plans are exempt from some managed care plan requirements in 42 CFR Part 438, but they must comply with the Patient Access API requirement. Section 438.9, which would be amended by this proposed exemption, identifies the regulations to which these plans are subjected.)

The Provider API for the individual patient use case would be codified in a new subsection (a)(1)(i) to the regulations for Medicaid fee-for-service programs (42 CFR 431.61), CHIP fee-for-service programs (42 CFR 457.731) and QHP issuers in FFEs (45 CFR 156.222). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

2. Bulk Data Provider Access API

CMS proposes that in addition to data exchange on individual patients, impacted payers must maintain a standards-based Providers Access API using the HL7 FHIR Bulk Data Access (Flat FHIR) specification at 45 CFR 170.215(a)(4) to accommodate exchange of data on multiple patients at the same time. The Bulk Data Provider Access API would make the same data available as the Provider Access API for individual patient requests. It believes that having separate solutions is needed for different circumstances. For example, a large group practice or health system may benefit from using the bulk specification to update records annually while an individual provider within the health system might want quick access to an individual patient's information.

Like the other provisions of this proposed rule, the Bulk Data Provider Access API would be required by January 1, 2023 (and the rating period beginning on or after that date for Medicaid managed care plans and CHIP managed care entities). CMS recognizes that this proposal may be seen as burdensome because it could involve building multiple APIs to share data between providers and payers.

CMS discusses its experience with providing bulk patient data using the HL7 FHIR Bulk Data Access (Flat FHIR). It uses the Flat FHIR for the Beneficiary Claims Data API (BCDA) which allows Accountable Care Organizations under the Medicare Shared Savings Program to retrieve Medicare claims data for their beneficiaries. In addition, the Data at the Point of Exchange pilot

program (DPC) allows providers to access synthetic Medicare FFS claims data and integrate it into their electronic health records or other IT systems they use to support patient care.

Comments are sought on several issues: Whether the timeline is feasible; whether the benefits of the Bulk Data Provider Access API outweigh the costs; on having the Provider Access API available with and without the use of the bulk data access specification. CMS also asks whether it should require payers to implement just one API that leverages the HL7 FHIR Bulk Data Access (Flat FHIR) specification for when they are requesting data for one patient or more than one patient instead of finalizing its proposal for payers to have one solution that does not use the bulk specification for individual patient requests and have a second solution that uses the bulk specification for requests involving more than one patient.

CMS discusses the potential for state Medicaid and CHIP programs to access federal matching funds to support implementation of the Provider Access API as administrative expenses. For Medicaid this could be the standard 50 percent matching rate or higher rates for expenditures related to developing and installing of mechanized claims processing and information retrieval systems (90 percent) or operating claims processing and information retrieval systems (75 percent).

The Provider API for the Bulk Data Access approach would be codified in a new subsection (a)(1)(ii) to the regulations for Medicaid fee-for-service programs (42 CFR 431.61), CHIP fee-for-service programs (42 CFR 457.731) and QHP issuers in FFEs (45 CFR 156.222). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

3. Attribution

Payers would be required to establish and maintain a process to facilitate generating each provider's current beneficiary roster to enable payer-to-provider data sharing via the Provider Access API. CMS notes that there are multiple approaches that payers could use to identify the patients whose information would be requested and seeks to give payers the opportunity to establish a process that works best for their provider relationships. It notes that the Patient Access final rule provides privacy and security technical standards offering a baseline of protection. For example, the API would allow payers to determine if a provider requesting data is who they say they are through authorization and authentication protocols.

To facilitate data sharing, providers would have to provide payers with a list of patients for whom data are requested. CMS allows flexibility for how payers would generate this list. It notes that whatever process payers put in place must be compliant with HIPAA privacy and security rules and must provide the information needed to complete their payer-specific compliance processes. **CMS seeks comment on whether payers would prefer CMS to require a specific process across payers.** For example, the process it is using in the DPC pilot would allow providers to electronically self-attest a roster of patients for whom they have an active treatment need for data, which is checked against claims to verify the provider has furnished services to the patient. For new patients when there is no claims history, a payer could confirm a patient has an upcoming appointment scheduled.

The proposed attribution requirement would be codified in a new subsection (a)(2) to the regulations for Medicaid fee-for-service programs (42 CFR 431.61), CHIP fee-for-service programs (42 CFR 457.731) and QHP issuers in FFEs (45 CFR 156.222). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

4. Opt-in

Impacted payers would be allowed to have a process for patients (or their personal representative) to opt-in to use of the Provider Access API for data sharing between their payer and the providers who are currently providing them care or planning to provide them care. The proposed rule does not prescribe a method, but CMS is considering whether to suggest a specific process. One approach might be to have all payers engage in opt-in as part of annual notice or regular communication with patients regarding claims, and to permit opt-in through a variety of options such as phone, website, or an application.

CMS notes that under HIPAA, health plans need not obtain patient consent to share data with providers for purposes of treatment or care coordination. However, CMS believes that patient preferences should be honored and therefore sees value in possibly providing patients with options regarding which providers have access to their information under the proposed Provider Access API. **Comments are sought on several issues:** whether payers would prefer CMS to identify a specific process that all payers would be required to implement as part of the Provider Access API; whether stakeholders would prefer that CMS finalize an opt-out process instead of the proposed opt-in approach; whether the opt-in (or opt-out) should be optional; the associated benefits and burdens associated with the different approaches; and any other consideration that CMS should take into account in developing a final policy.

The proposed opt-in requirement for the Provider Access API would be codified in a new subsection (a)(3) to the regulations for Medicaid fee-for-service programs (42 CFR 431.61), CHIP fee-for-service programs (42 CFR 457.731) and QHP issuers in FFEs (45 CFR 156.222). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

5. Educational Resources for Providers

Payers would be required to provide educational resources for providers on how to request access to patient data though the Provider Access API for individual patients and bulk data requests. The information would need to be provided on the payer's website and through other mechanisms by which the payer normally communicates with providers. The resources would need to be in non-technical, simple, and easy-to-understand language.

The proposed requirement for educational resources would be codified in a new subsection (a)(4) to the regulations for Medicaid fee-for-service programs (42 CFR 431.61), CHIP fee-for-service programs (42 CFR 457.731) and QHP issuers in FFEs (45 CFR 156.222). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

6. Extensions and Exemptions for Medicaid and CHIP FFS Programs; Exception for QHP Issuers

CMS proposes extensions, exemptions, and an exception to the Provider Access API requirements:

- A process by which state Medicaid and CHIP FFS programs would be able to request a one-time extension of up to one year for implementation of the Provider Access API. An extension would be granted if CMS determines that the request (1) establishes the need for delay, such as due to lack of state funding; (2) demonstrates a good faith effort to implement the API as soon as possible; and (3) provides a clear plan to implement it no later than one year after the compliance date. **CMS seeks comment on whether it should require or use additional information or establish a different standard for evaluating and granting a request for extension.**
- A process for granting a one-year exemption to a requesting state where at least 90 percent of all covered items and services are provided through managed care or at least 90 percent of program enrollees are enrolled in managed care. A state meeting this exemption threshold would be expected to use an alternative means of electronic exchange and accessibility of information for beneficiaries served by the state's FFS program.
- A process for an FFE to grant an exception from the Provider Access API requirements for a QHP issuer; this would be parallel to the exception process provided under the Patient Access API requirement. Under the proposed process the issuer would include as part of its application for QHP certification a request for an exception and provide a narrative justification describing why it cannot meet the requirements for the applicable plan year, the impact of non-compliance on providers and enrollees, current means of providing the information to providers, and solutions and a timeline for compliance. The FFE would be able to grant the exception if it determines that making the health plan available on the FFE is in the interests of individuals in the state.

CMS does not propose an extension for Medicaid managed care plans and CHIP managed care entities because it believes they are actively working to develop the infrastructure to comply with API requirements of the Patient Access final rule. In addition, it believes many managed care plans are part of parent organizations that maintain multiple lines of business, and benefit from efficiencies in interoperability policies. **CMS seeks comment on several issues:** whether this belief in the ability of managed care parent organizations to achieve economies of scale is well-founded and whether an extension is warranted for certain managed care plans. CMS says it is open to considering an extension process for managed care plans. If one is finalized, it asks for input on what criteria should be used (e.g., enrollment size, plan type, other characteristic) and whether the process should be managed by the state or by CMS.

7. Statutory Authority for Provider Access API

For each of the impacted payers, CMS discusses the statutory authority under which it is proposing the Provider Access API policies. It reviews the rationale for the proposals.

C. Documentation and Prior Authorization Burden Reduction through APIs

This section of the proposed rule includes several proposals related to prior authorization. CMS intends these proposals to mitigate provider burden and improve care delivery to patients. The following proposals are made and are detailed further below:

- Impacted payers would be required to implement a Document Requirement Lookup Service (DRLS) API.
- Impacted payers would be required to implement a Prior Authorization Support (PAS) API. This API would include transmission to providers of an indication of whether the payer approves, denies, or requests more information on a prior authorization request, and in the case of a denial, a specific reason would be required.
- Medicaid and CHIP FFS programs and managed care plans and entities would be required to provide notice of prior authorization decisions as expeditiously as the patient's health condition requires, no later than 72 hours after receiving a request for expedited decision and no later than 7 days for standard decisions.

CMS provides background on its development of these proposals, citing specific input from stakeholders through listening sessions, hearings, meetings, and reports. Prior authorization, which in some programs is referred to as pre-authorization or pre-claim review, requires a provider to obtain approval from a payer before providing care and prior to receiving payment for delivering items and services. Stakeholders have cited the variation in payer policies, workflow challenges and technical barriers as all contributing to making prior authorization a major source of burden on providers and payers, a cause of provider burnout, and a health risk to patients when it causes a delay in needed care.

Existing HIPAA transaction standards for the electronic exchange of information by covered entities include a prior authorization transaction standard (i.e., standards for referral certifications and authorizations). CMS notes that although payers are required to use to X12 Version 5010x217 278 (or X12 278) standard for electronic prior authorization transactions, it has not achieved a high adoption rate by covered entities.[4] **CMS believes that its proposals in this rule could support increased use of the standard, but also seeks comments on whether there are other steps it could take to further implementation of the X12 278 standard and what challenges would remain if it were more widely used.** CMS notes that new operating rules for the prior authorization standard are under consideration at HHS and that if they are adopted CMS will evaluate their impact on the proposals in this rule.

[4] CMS cites data from the Council for Affordable Quality Healthcare indicating that 14 percent of respondents indicated they were using the standard in a fully electronic way; 54 percent were conducting electronic prior authorization using web portals, Integrated Voice Response and other options, and 33 percent were fully manual (phone, mail, fax, and email). https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf?token=SP6YxT4u

1. Requirement for Payers: Documentation Requirement Lookup Service API

CMS proposes that impacted payers implement and maintain a FHIR-based DRLS API that conforms with the HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0 and the HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0 IG, populated with the payer's 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. The DRLS API would be required to meet the same technical standards, API documentation requirements, and discontinuation and denial of access requirements as apply to the Patient Access API (and as proposed for the other new APIs proposed in this rule).

CMS believes that the DRLS API would make prior authorization requirements and documentation requirements more accessible and transparent to providers at the point of care and would address this concern as identified by providers. Providers could use the API to query the prior authorization requirements for specific items and services to identify documentation requirements and could use the API to complete electronic forms and templates or to link elsewhere to submit the documentation. **CMS seeks comments on how to encourage development of functions within provider electronic health record systems to maximize the potential of the DRLS API, and also whether and how to require or incentivize providers to use the payer's DRLS API in their workflows.**

In addition, CMS sees benefits to payers as use of the DRLS API could reduce the number of unnecessary requests, minimize follow-up, and reduce denials and appeals. It notes that by the time this API would be required payers will have implemented the Patient Access API, and that infrastructure would provide the technology needed to support this proposed new API. CMS considered implementing the DRLS API in phases but concluded that the January 1, 2023 implementation date would be instrumental to increasing use of electronic prior authorization.

Comments are sought on several issues, including a potential short-term solution to address the challenge of accessing payer requirements for prior authorizations. CMS is interested in learning how payers currently communicate prior authorization requirements, and on the potential for payers to post, on a public-facing website, their list of items and services for which prior authorization is required, populate the website with their associated documentation rules as an interim step while they implement the DRLS and whether this would provide a satisfactory interim solution to the challenge of accessing payer requirements for prior authorizations in advance of implementing the DRLS API.

The proposed DRLS API would be newly codified in a subsection (a)(1) for Medicaid fee-for-service programs (42 CFR 431.80), CHIP fee-for-service programs (42 CFR 457.732) and QHP issuers in FFEs (45 CFR 156.223). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

2. Requirement for Payers: Prior Authorization Support (PAS) API

CMS proposes to require that impacted payers implement a Prior Authorization Support (PAS) API to facilitate 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 seeks authorization. The PAS API would need to conform to the HL7 FHIR Da Vinci Prior Authorization Support IG. When sending a response to a request for prior authorization, the payer would need to include information on whether it approves (and for how long), denies, or requests more information on the request. CMS believes that this API would employ API technology while maintaining compliance with the HIPAA transaction standard, and would accelerate adoption of electronic prior authorization, especially when paired with the DRLS API. As explained by CMS the API would involve an intermediary that would translate requests and responses into a HIPAA compliant X12 278 transaction.

With respect to denial of a prior authorization request, the proposal would require impacted payers to include a specific reason for the denial with all prior authorization decisions, regardless of the method used to send the decision. CMS suggests that the reason for denial may indicate that the necessary documentation was not provided, that the services were determined not to be medically necessary, or that the patient exceeded allowed limits on care for the item or service. CMS believes that a clear and specific reason for denial would support its efforts to reduce the burden of prior authorization on payers, providers and even patients.

CMS believes this proposal would improve the electronic data exchange between impacted payers and providers once provider practice management systems or EHRs connect with the API. It believes that providers are eager to access this type of technology to replace the numerous web portals and fax numbers used to submit prior authorizations requests currently. As a result, CMS also believes that EHR developers would increasingly adapt functionality to integrate interaction with the PAS API directly into a provider's workflow. **Comments are sought on steps that HHS could take to educate providers on the benefits of these APIs and incentivize their use, as well as on opportunities to encourage health IT developers to implement these functions within EHRs, including a possible future addition of certification criteria to the ONC Health IT Certification Program.**

CMS discusses the potential for federal matching funds to support implementation of the DRLS and PAS APIs. See the discussion above (section II.B.2) regarding the Bulk Data Provider Access API.

The proposed PAS API would be newly codified in a subsection (a)(2) for Medicaid fee-for-service programs (42 CFR 431.80), CHIP fee-for-service programs (42 CFR 457.732) and QHP issuers in FFEs (45 CFR 156.223). It would apply to Medicaid managed care plans and CHIP managed care entities through cross references.

3. Medicaid and CHIP Managed Care Notice Requirements for Prior Authorization Denial

CMS notes that under existing regulations, Medicaid and CHIP managed care plans and entities are subject to requirements for notifying providers and patients when they make an adverse

decision on a prior authorization request. The proposal above to require that the payer provide a reason for the denial would not replace these requirements. Instead, it would supplement those notice requirements and allow for an efficient method of providing the information. If a payer transmits to providers via the PAS API an indication of whether the payer approves, denies, or seeks more information on a prior authorization request, it would satisfy the current requirements for notice to providers at §438.210(c) and (d). It would have no effect on the requirements for notice to enrollees, however (§438.210(c) and (d) and §438.404). Until adoption of the PAS API, CMS encourages managed care plans to ensure that their prior authorization policies and practices do not impede timely access to care or affect network adequacy.

4. Request for Comment on Prohibiting Post-Service Claim Denials for Items and Services Approved Under Prior Authorization

For purposes of possible future rulemaking, CMS seeks comments on issues regarding denials of provider claims for approved prior authorizations. Providers have expressed concern about the time spent resolving these denials and report that patients sometimes receive unexpected bills as a result. CMS seeks comments from payers and other stakeholders on the issues that could inform a future proposal to prohibit impacted payers from denying claims for covered items and services for which a prior authorization has been approved.

CMS asks what requirements would be appropriate to include in a policy to ensure that claims that meet certain guidelines for approved authorizations are not denied. In addition, it seeks comment on whether it would be important that the patient be enrolled with the payer at the time the items or services were provided, or that certain conditions exist for the provider's contract status with the payer. Also requested are other requirements that would be appropriate to include in a policy to ensure that the claims that meet certain guidelines for approved authorizations are not denied.

Input is also sought on the criteria payers could use to deny claims once they are submitted to the claims processing system. For example, do payers deny claims when there is reliable evidence of technical errors, a duplicate claim for the approved item or service, or evidence that an approved prior authorization was procured based on material inaccuracy or by fraud? Commenters are encouraged to provide examples of program integrity practices used by payers to identify and address fraudulent claims.

Further, CMS asks whether all payer types should be required to comply with a policy to prohibit payers from denying a claim for payment after approving a prior authorization request for covered items and services, or if any payer types should be excluded, and for what reasons.

Finally, input is sought on the unintended consequences, cost implications, and cost estimates related to prohibiting a prior authorized claim from being denied, to the extent data can be provided. CMS is interested in what legitimate reasons for denial could be restricted by the adoption of specific criteria. Payers are invited to comment on whether such a policy could increase improper payments or program costs, decrease state use of prior authorization, or impact enforcement of third-party liability.

5. Requirements for Prior Authorization Timelines and Communications

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 no circumstances later than 72 hours of receiving a request for expedited decisions, and no later than 7 calendar days after receiving a request for standard decisions. For Medicaid managed care plans, CMS also proposes to maintain that an extension of 14 days is authorized if the enrollee requests it or a health plan determines additional information is needed. The terms "standard" and "expedited" are used in existing Medicaid regulations at §438.210(d). An expedited prior authorization is needed when failure to decide could jeopardize the health or life of the patient; a standard prior authorization is for non-urgent items and services.

In making this proposal, CMS discusses concerns raised by providers regarding excessive wait times for prior authorization decisions, which often delay the delivery of services to patients. In a survey by the American Medical Association 28 percent of physicians stated that delays in care due to the prior authorization process led to serious adverse events, including death, to patients.

Existing Medicaid and CHIP requirements for the timing of responses to prior authorization requests are reviewed. Effective with prior authorization decisions beginning on January 1, 2023, the proposal would modify these requirements to require a notice of a prior authorization decision no later than 7 calendar days after receiving a request for a standard decision. CMS did not propose changes to the timeline for expedited decisions for Medicaid managed care plans and CHIP managed care entities, which already apply a 72-hour timeframe with an opportunity to extend that by up to 14 days under certain circumstances. Regulations establishing timelines for prior authorization decisions are found at §428.210(d)(2) and §457.1230(d). CMS notes states are not prohibited from complying with more stringent decision timelines if required under state law.

The specific changes to regulatory text to accomplish this proposed policy are identified and discussed in the proposed rule. In addition, CMS proposes a series of clarifications to ensure that existing beneficiary rights apply. CMS proposes to make explicit that existing Medicaid notice and fair hearing rights apply to Medicaid FFS prior authorization decisions. That is, under current regulations partial or total denial of a prior authorization request is appealable through a state fair hearing. In addition, under the proposed rule effective January 1, 2023, the state would have to provide an individual at least 10 days notice prior to taking any action that includes termination, suspension, or reduction in benefits or services for which there is a current approved prior authorization and afford the beneficiary the right to continuation of services pending resolution of the state fair hearing. The state would also have to provide notice to the beneficiary when it fails to reach a decision on a prior authorization request within the proposed timeframes. CMS proposes that regulatory changes be effective with publication of the final rule but notes that any notice or fair hearing rights based solely on the new policies in this rule would take effect with those policies (e.g., January 1, 2023).

Further changes would make clear that the existing requirements for the content of notices to beneficiaries (431.210) would apply to changes in benefits or services *for beneficiaries receiving*

medical assistance. (Currently the language refers to changes in eligibility or change in benefits or services.) The intention of the proposed changes is to ensure that individuals receiving medical assistance who are denied benefits or services because of a prior authorization decision would receive a notice clearly explaining the reasons for denial. **Comments are sought on how states currently apply notice and fair hearing rights to prior authorization requests, and whether CMS should, in future rulemaking, not require fair hearing rights for prior authorization denials.**

CMS does not propose to extend these timeframes to QHPs on FFEs because it believes that to do so in light of existing standards at 45 CFR 147.136(b)(3) regarding internal claims and appeals standards could result in burdensome and conflicting regulatory standards. However, **comments are sought on whether having different processing timelines for QHPs on FFEs would be operationally feasible for issuers, or unintentionally increase burden.**

Additional comments are sought on related topics. Regarding the proposed timeframes, CMS asks:

- Are alternative timeframes feasible or appropriate for prior authorization for items and services?
- Under what circumstances could payers approve an expedited prior authorization in less than the proposed 72 hours? Are there circumstances in which a payer should be required to approve an expedited prior authorization in 24 hours for items and services other than prescription or outpatient drugs? What are the operational and system requirements for a more streamlined scenario for prior authorization approvals?
- Under what circumstances could an approval be provided in less than 7 calendar days for a complex case?

Regarding process challenges with prior authorization, CMS asks:

- Are there scenarios that could be appropriate to support temporary coverage of services, such as, temporary access to DME, while the patient waits for an authorization during the 14-day review timeframe?
- What policy conditions might be necessary to include in such authorization determinations? Commenters are encouraged to provide examples of best-case and worst-case scenarios, and explain what changes in process, policy, or technology would be necessary.

6. Extensions and Exemptions for Medicaid and CHIP FFS Programs; Exception for QHP Issuers

For state Medicaid and CHIP FFS programs, CMS proposes opportunities for a one-time extension or annual exemptions from the DRLS API and the PAS API requirements that are parallel to those described in section II.B.6 above with respect to the Provider Access API requirements. Similarly, for QHP issuers on the FFEs, an issuer may request an exception to the requirements for the DRLS API or the PAS API under the same process discussed above with respect to the Provider Access API. The extensions and exemptions are not proposed for Medicaid and CHIP managed care plans and entities.

7. Public Reporting of Prior Authorization Metrics

Impacted payers would be required to publicly report certain prior authorization metrics on their websites. For Medicaid and CHIP FFS programs, the reported data would be required at the state level. It would be reported at the plan level for Medicaid and CHIP managed care and at the issuer level for QHP issuers on the FFEs.

Specifically, impacted payers would be required to publicly report at least annually the following metrics. Note that in this proposed rule the term items and services excludes prescription drugs and covered outpatient drugs. The separate reporting of items and services would result in percentages for items and services as two separate prior authorization categories.

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

Under the proposal, beginning March 31, 2023, the data would be reported publicly annually, by the end of the first calendar quarter each year for the prior year's data. For example, for all impacted payers, all available data for calendar year 2022 would be publicly reported by the end of the first calendar quarter of 2023, or by March 31, 2023.

CMS says that it may consider proposing in future rulemaking to use these data to help develop quality measures to incorporate into quality star ratings across certain payer programs over time, specifically for QHP issuers on the FFEs.

CMS believes that public reporting of this information would help inform patients and providers about payers. Patients may consider access to care in choosing a plan, and providers may consider information on prior authorization decisions useful when deciding whether to contract with a plan or join a network.

Public reporting of prior authorization metrics would be codified for Medicaid fee-for-service programs (42 CFR 440.230(d)(2)), CHIP fee-for-service programs (42 CFR 457.732(a)(3)), Medicaid managed care plans (42 CFR 438.210(f)), CHIP managed care entities (457.1233(d)(2)) and QHP issuers in FFEs (45 CFR 156.223(a)(3)).

8. Request for Comment on "Gold-Carding" Programs for Prior Authorization

CMS seeks comment on "gold-carding" or similar programs under which payers relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. It believes that gold-carding programs could help alleviate provider burden related to prior authorization and facilitate more efficient and prompt delivery of health care services to beneficiaries. CMS emphasizes the importance of reducing provider burden and 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.

In particular, comments are sought for potential future rulemaking on the incorporation of gold-carding into star ratings for QHP issuers on the FFEs. CMS has also considered proposing gold-carding as a requirement for payer prior authorization policies and seeks comment on how such programs could be structured.

9. Additional Requests for Comment

Comments are sought on the following additional topics:

- Whether there should be certain restrictions regarding requirements for repeat prior authorizations for items and services for chronic conditions, or whether there can be approvals for long-term authorizations. CMS asks what alternative programs are in place or could be considered to provide long-term authorizations for terminal or chronic conditions.
- Whether a prior authorization decision should follow a patient when they change from one QHP on the Exchange to another, or to another health plan impacted by this proposed rule, and under what circumstances that prior authorization could follow a patient from payer to payer.
- Whether prior authorizations should be valid and accepted for a specified amount of time, and who should determine how long an existing approved prior authorization from a previous payer should last and whether prior authorization should be regulated by amount of time and/or by condition.
- Solutions to standardizing prior authorization forms, including the possibility of developing an HL7 FHIR-based questionnaire for prior authorization requests.
- How to potentially phase out the use of fax technology to request and send information for prior authorization decisions and what barriers must still be overcome to accomplish this goal.

10. Statutory Authorities to Require Prior Authorization Burden Reduction Proposals

CMS reviews the rationale for the proposals made regarding prior authorization and the underlying statutory authority for each of the impacted payer types.

D. Payer-to-Payer Data Exchange on FHIR

The Patient Access final rule requires payer-to-payer data exchange, effective January 1, 2022 for MA organizations, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs. (Medicaid and CHIP FFS programs are not subject to this requirement.) The requirement is that affected payers must maintain a process for the electronic exchange of the data classes and elements included in the USCDI Version 1 data set. Under this payer-to-payer data exchange, with the approval and at the direction of a current or former enrollee (or their representative), a payer must (1) receive this information from another payer that had covered the enrollee within the preceding 5 years and incorporate it into its records about the enrollee, (2) with respect to current enrollees and for up to 5 years after disenrollment, send data to any payer that currently covers the enrollee or to which the enrollee specifically requests the data be provided. When a payer is sending data to another payer, data it previously received from other payers is to be sent in the electronic form and format in which it was received. The requirement is limited to data with a service date on or after January 1, 2016. To satisfy this requirement, payers may use multiple methods for electronic exchange of information – a standards-based API was encouraged but not required. CMS indicated that it was considering a requirement for an API-based payer-to-payer data exchange for future rulemaking.

In this rule CMS proposes to amend the payer-to-payer data exchange requirement in several ways:

- Payer-to-payer data exchange requirements would be extended to include Medicaid and CHIP FFS programs.
- A FHIR-based API would have to be used for payer-to-payer exchange; the API would have to conform to certain IGs.
- Data exchange would be expanded to include claims and encounter data (excluding cost information), the USCDI clinical data currently required, and certain data on active and pending prior authorization requests. Elsewhere in this rule, CMS proposes to make this information available through FHIR-based APIs for patients and providers. (See sections II.A and II.B above.)
- Payers would be required to facilitate the option for payer-to-payer data sharing at the time of a patient's enrollment.

1. Payer-to-Payer Data Sharing in Medicaid and CHIP

Medicaid and CHIP FFS programs were not included in the Patient Access final rule payer-to-payer data exchange requirement. CMS viewed it as potentially challenging for states to meet in the required timeframe due to budget and resource constraints, and it wanted states to focus on meeting the Patient Access and Provider Directory API requirements.

Because it is now proposing that payers use a FHIR-based API for payer-to-payer data exchange, CMS believes that this requirement would not be as burdensome to states. By the time the proposed requirement would be in effect, Medicaid and CHIP programs must already have implemented the Patient Access API requirement, which makes this proposed new API less burdensome. CMS believes that the payer-to-payer API would make administration of Medicaid

and CHIP more effective and reduce burden for patients and providers. For example, duplication of tests may be reduced.

CMS discusses the potential for federal matching funds to support implementation of the Payer-to-Payer API. See the discussion above (section II.B.2) regarding the Bulk Data Provider Access API.

This proposed application of the Payer-to-Payer data sharing requirement would be codified at 42 CFR 431.61(b) for Medicaid FFS programs and 457.731(b) for CHIP FFS programs.

2. Enhancing the Payer-to-Payer Data Exchange: Payer-to-Payer API

CMS proposes that the payer-to-payer data exchange requirement be modified to require that the data exchange take place via an API and to expand the data to be made available to include not only the USCDI version 1 data, but also claims and encounter data maintained by the payer with a service date on or after January 1, 2016 as well as information on pending and prior authorizations as proposed for addition to the Patient Access API (section II.A above). The Payer-to-Payer API would be required to meet the same technical standards and base content and vocabulary standards used for the Patient Access API. CMS believes that this data exchange can improve operational efficiencies, reduce unnecessary care, reduce care costs, and improve patient outcomes.

CMS notes that although the receiving payer would be required to incorporate the data it receives from other payers into its records about the patient, it is not proposing that the receiving payer must act on the information it receives. The receiving payer would have no obligation to review, use, update, validate or correct data received, although it would not be precluded from doing so.

Exchange of cost data would not be required; CMS says that this information has only limited benefits for care coordination. It believes that the addition of claims data to the USDCI clinical data offers more information on the patient's care history to support care coordination and efficient operation. Likewise, it believes the addition of pending and active prior authorization information could be highly valuable and improve continuity of care. While payers would not need to consult this information, it would be in the patient's record and available to be shared by the payer with the patient's providers.

CMS seeks comment on an alternative under which payers would be required to honor a previous payer's active prior authorization decisions for a period of time (e.g., 30, 45, or 60 days) after a new patient is enrolled. It asks for comments on whether there are situations where this may not be possible or appropriate, and why.

CMS notes that under this proposed rule, the same data elements would be exchanged through three APIs: the previously adopted Patient Access API, the proposed new Provider Access API, and the proposed new Payer-to-Payer API. The Patient Access API provides the foundation necessary to share claims, encounter, and clinical data, and CMS expects that payers would be able to build the additional infrastructure after 2021 when the Patient Access API has been implemented.

However, with respect to the proposed addition of sharing data on prior authorizations, CMS notes it is proposing that the Payer-to-Payer API conform to the HL7 FHIR Da Vinci Payer Coverage Data Exchange Implementation Guide (PCDE IG), which is different from the IGs required for the Patient and Provider Access APIs (PDex IG). It believes that the PCDE IG addresses data sharing between payers more specifically; the PDex IG is better suited for exchange from payer to provider and patients. CMS does not believe requiring use of both IGs would add significant burden on payers.

The proposed requirements for the Payer-to-Payer API would modify existing regulations at 42 CFR 438.242(b)(7) for Medicaid managed care plans, 42 CFR 457.1233(d)(4) for CHIP managed care entities, and 45 CFR 156.221(f)(2) for QHP issuers on the FFEs. It would be codified at 42 CFR 431.61(b) for Medicaid FFS programs and 42 CFR 457.731(b) for CHIP FFS programs.

3. Payer-to-Payer API: Sharing Data at Enrollment

CMS proposes that in addition to the payer-to-payer data exchange initiated by the patient as discussed above, impacted payers would be required to offer patients a new Payer-to-Payer API data exchange opportunity at the time of enrollment. Under the proposal, when a patient newly enrolls with an impacted payer, they would be given the opportunity to opt-in to having the new payer obtain data from their previous payer. This opportunity would be given during the first calendar quarter of the year following a patient's enrollment during the payer's open enrollment period. For patients who opt into the data exchange opportunity, the new payer would be required to request the data using the HL7 FHIR Bulk Data Access (Flat FHIR) within one week of the end of the enrollment period or the first calendar quarter of each year. The previous payer would be required to respond to the request within one business day. Payers must continue to comply with obligations as a HIPAA-covered entity.

Impacted payers would be required to have a process to obtain from a new enrollee the name of their previous payer and any concurrent payer. **CMS seeks comment on potential approaches to meeting this requirement.** It expects that many payers have a process in place to identify concurrent payers for purposes of coordination of benefits or to implement Medicare Secondary Payer requirements. CMS seeks to allow payers to continue to use these processes if that is beneficial.

Impacted payers would also need to establish a process to allow enrollees to opt-in to the payer-to-payer data sharing at the time of enrollment. For payers that do not have a defined enrollment period, this opt-in opportunity would have to be made each year by the end of the first calendar quarter. If enrollees do not opt-in, the payer would have no obligation to share their data through the enrollment data sharing Payer-to-Payer API process. Outside the enrollment requirement, patients always have the option to request payer-to-payer data exchange under current requirements, as amended by the proposal to establish a requirement for a FHIR-based Payer-to-Payer API described above.

In addition to the new enrollment provision, when an enrollee has concurrent coverage with two or more payers, CMS proposes that the impacted payers make the patient's data available

quarterly to the other concurrent payers; enrollees would be given the opportunity to opt-in to this quarterly data exchange. **CMS seeks comment on the frequency of payer-to-payer data exchange for enrollees with concurrent coverage, whether payers prefer flexibility in determining the process for facilitating patient opt-in to this quarterly data sharing, and if there are additional considerations that CMS should take into account.**

CMS encourages all payers, including employer plans and others not impacted by this proposed rule, to consider the value of implementing a Payer-to-Payer API to broaden the benefits of data sharing. It is considering next steps for Medicare FFS to participate in such a data exchange with all interested payers.

CMS seeks comments on several issues regarding how best to operationalize this proposal across impacted payers. It asks whether the proposal provides for the best time for data sharing for payers with a dedicated annual open enrollment period**.** CMS believes that for these payers, the use of the bulk specification at certain times for this data exchange would provide efficiencies. It asks whether the proposed timeframes for the new payer requesting the data – within one week of the enrollment period or other defined period ending – and the old payer sending these data within one business day are the optimal timeframes; it states that the data should be made available to the new payer as quickly as possible. CMS also seeks comment on other factors it should consider regarding the process and timeline for the proposed Payer-to-Payer API data sharing at enrollment. Finally, as it did with respect to the Provider Access API, (section II.B above) CMS seeks comment on the tradeoffs and benefits of having the Payer-to-Payer API available with and without the use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification.

The proposed requirements for payer-to-payer data sharing at enrollment would appear at 42 CFR 431.61(c) for Medicaid FFS programs, 457.731(c) for CHIP FFS programs, 438.242(b)(7) for Medicaid managed care plans, 457.1233(d)(4) for CHIP managed care entities, and 45 CFR 156.222(b) for QHP issuers on the FFEs.

4. Extensions and Exemptions for Medicaid and CHIP FFS Programs; Exception for QHP Issuers

For state Medicaid and CHIP FFS programs, CMS proposes opportunities for a one-time extension or annual exemptions from the Payer-to-Payer API requirements that are parallel to those described in section II.B.6 above with respect to the Provider Access API requirements. Similarly, for QHP issuers on the FFEs, an issuer may request an exception to the requirements for the Payer-to-Payer API under the same process discussed above with respect to the Provider Access API. The extensions and exemptions are not proposed for Medicaid and CHIP managed care plans and entities.

5. Statutory Authority for Payer Exchange Proposals

For each of the impacted payers, CMS discusses the statutory authority under which it is proposing the Provider Access API proposals. It reviews the rationale for the proposals.

E. Adoption of Health IT Standards and Implementation Specifications

As noted in each of the earlier sections, the ONC proposes in this rule to require adoption of specific IGs in support of the API provisions that CMS is proposing in this rule. The proposal would modify the regulatory text at 45 CFR 170.215 to adopt the specific IGs. Links to the latest version of each IG are provided. Minor changes to the regulatory text are proposed which ONC says would support greater clarity in the short descriptions of previously adopted standards and implementation specifications at §170.215.

ONC stresses that it is not proposing new or revised certification criteria under the ONC Health IT Certification Program, and neither is it proposing to require testing and certification to these implementation specifications. ONC believes that the proposed adoption of the IGs is an important addition to the interoperability specifications and would support future alignment of the nationwide health IT infrastructure. In addition, federal alignment and coordination to federal activities across a wide range of systems, use cases, and data types would be supported.

In this section of the proposed rule, ONC's statutory authority for these proposals is discussed and the rationale for the proposals is reviewed. The discussion includes the role of standards development organizations, ONC's Interoperability Standards Advisory, and the Health Information Technology Advisory Committee (HITAC). In particular, several recommendations as recent as 2020 from the HITAC relate to proposals in this rule, including work on standards for integration of prior authorization and merging of clinical and administrative data. Coordination between ONC and CMS as well as ONC and other agencies is discussed.

III. Requests for Information

A. Methods for Enabling Patients and Providers to Control Sharing of Health Information

Stakeholders assert that empowering patients and providers to use data to make informed healthcare decisions includes allowing both of those groups to have a say in what data are shared, when and with whom. Patients want the right to choose the data elements that may be shared and to have the ability to opt out of some information exchanges. Providers want the right to choose if some or all of a patient's data should be shared. Some stakeholders have raised concerns about whether existing IT systems, processes, or standards have matured sufficiently to protect sharing of patient health information. **In light of these issues, CMS requests feedback on the following questions:**

- Patient Engagement and Provider Discretion. What role should patients and providers play in data segmentation decisions? Are there mechanisms currently in place for documenting these preferences? Would there be negative consequences for patients who are unable to or do not state their preferences? How can patients be engaged in these decisions without burdening them? Are there specific situations or considerations that should limit how an impacted entity responds to a data segmentation request? Are there unintended consequences of data segmentation requests and if so, how can they be addressed?

- Methods and Readiness. Are there examples of effective tools and methods for patients and providers to control access to portions of patients' health data? What is the readiness and feasibility of such tools or methods?

- Resource Burden. Would requiring the ability to segment data by, for instance, data tagging, place additional burden on clinical providers? What are possible solutions to address these concerns?

- Current Patient Consent Practices. How do current consent practices inform patients of opportunities for patient engagement and provider discretion in responding to patient requests? What technology and policy gaps exist for achieving successful segmentation practices?

- FHIR Utility. How can the data segmentation capabilities of existing FHIR standards be improved? What is the state of efforts to address data segmentation on FHIR or other standards? What are the key gaps or constraints that exist within those efforts?

- Technical Considerations. What general data segmentation strategies and lessons learned could be leveraged from programs like the Substance Abuse and Mental Health Services Administration's (SAMSHA) Consent2Share and HL7 Data Segmentation for Privacy (DS4P)? How can existing tools, resources, and approaches with data segmentation be used to inform new approaches or strategies?

- Patient Options. Should data senders try to honor preferences but retain the flexibility to deny the preferences in certain situations? For example, the HIPAA Privacy Rule requires a covered entity to permit an individual to request restrictions on the entity's uses and disclosures of PHI, but only requires the entity to agree to the request in limited circumstances (see 45 CFR 164.522(a)(1)(vi)).

- Current Segmentation Efforts. CMS seeks stakeholder input from individuals who have implemented or piloted patient-controlled segmentation models, individual provider-controlled models, or other related models or tools. What prevents patients or providers from recording, maintaining, or using a patient's privacy preferences when exchanging health information? How can data segmentation decisions be automated? Are there processes or workflows related to patient privacy preferences, consent, or data segmentation that could be improved by automation and/or standardization?

B. Electronic Exchange of Behavioral Health Information

CMS describes several factors that may have contributed to lower EHR adoption rates among behavioral health providers when compared to that of other types of providers. For example, the HITECH Act only made incentive payments for the adoption and meaningful use of certified EHR technology available to certain eligible professionals excluding many types of non-physician behavioral health providers.

Comments are sought on ways to support electronic data exchange of behavioral health information between and among behavioral health providers, other providers, and patients, as well as how to inform and support the movement of health data to behavioral health providers for their use to inform care and treatment of behavioral health services. **Specifically, CMS seeks comments on the following questions:**

- Can applications using FHIR-based APIs facilitate electronic data exchange between behavioral health providers and with other health care providers and patients, without greater EHR adoption? What opportunities do FHIR-based APIs provide to bridge the gap? What needs might not be addressed by the use of applications with more limited functionality than traditional EHRs?

- What levers could CMS use to facilitate greater electronic health data exchange among behavioral health providers? What are their associated costs, resources, and/or burdens?

- Are there particular considerations for electronic data exchange for behavioral health providers who practice independently, are community-based, are non-traditional providers, or are in rural areas? How could an API-based solution help address these considerations?

- Are there state or federal regulations or payment rules that have created barriers to technical integration of systems within these practices? What additional policy issues, technical considerations, and operational realities should be considered when looking at ways to facilitate the secure electronic exchange of health information maintained by behavioral health providers including sensitive health information?

- What levers and approaches could CMS use to facilitate greater electronic health data exchange from and to community-based health providers including use of relevant health IT standards as feasible? What are their associated costs, resources, and burdens?

C. Reducing Burden and Improving Electronic Information Exchange of Prior Authorization

1. Electronic Prior Authorization for Medicare and Medicaid-Participating Providers and Suppliers

CMS describes some of its efforts to encourage the latest advances in health information technology and interoperability. It has identified electronic prior authorization as an area that could provide significant opportunities for health care system efficiency and improvements to direct patient care. Gaps in current prior authorization processes include requirements that do not reside within a provider's EHR, inconsistent submission methods for prior authorization requests, processes that include paper forms or manual data reentry, and multiple routes for obtaining prior authorization depending on payer, item or service, or provider.
Additional information is sought on the overall electronic prior authorization process, the impact of this process on patient health and safety issues, and whether the hospital (and other providers and suppliers) condition of participation (CoP) requirements are a good vehicle to achieve

adoption and use of electronic prior authorization requests. CMS plans to use the responses to the following questions in evaluating revisions to the hospital and CAH CoP requirements related to electronic prior authorization. **Specifically, CMS asks:**

- What are the current barriers to transmitting prior authorization requests and receipts electronically? What actions could CMS and/or industry take to remove barriers?

- Do current methods for electronic transmission of prior authorization requests, including the adopted standard, and any that have been established and maintained by third-party health care insurers (including Medicare) provide for efficient and timely request and receipt of prior authorization decisions?

- Would the CMS CoP and Conditions for Coverage requirements for hospitals and other providers and suppliers be the appropriate lever by which CMS should propose new or additional provisions to require the electronic request and receipt of prior authorization decisions? If so, under which provisions would this best be accomplished?

2. Request for Information: Future Electronic Prior Authorization Use in the Merit-Based Incentive Payment System (MIPS)

CMS is considering the addition of an improvement activity for the Merit-Based Incentive Payment System (MIPS) that would utilize a Prior Authorization Support API to facilitate submitting and receiving electronic prior authorization requests and decisions **and seeks comments in the following areas**:

- Is this an activity that stakeholders identify as improving clinical practice or care delivery?

- When effectively executed, is implementation of such technology and use of these standards likely to result in improved outcomes?

    - If yes, should this activity be assigned a medium- or high-weight? CMS refers readers to the CY 2019 PFS final rule where high-weighting for activities that directly address areas with the greatest impact on beneficiary care, safety, health, and well-being and/or is of high intensity, requiring significant investment of time and resources was discussed.

- If the addition of a MIPS improvement activity incorporating the use of a Prior Authorization Support API would not encourage clinicians to use electronic prior authorization solutions, are there other ways to incentivize their use?

- 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 API? What are the primary

considerations for developing such a measure and how would the measure require the use of certified EHR technology?

- Should the PAS IG be incorporated into potential future certification requirements for health IT under the ONC Health IT Certification Program?

- Should CMS consider additional measures and activities under MIPS Quality, Cost, or Improvement Activities performance categories involving FHIR-based electronic prior authorization solutions? If so, what are the primary considerations for developing such measures and activities?

- What other approaches should CMS consider to help support clinician use of electronic prior authorization solutions?

D. Reducing the Use of Fax Machines

In continuing to identify areas to increase efficiency and implement secure electronic data exchange, CMS notes that the historical reliance on fax technology has resulted in inefficiencies. Fax documents are not easily integrated into electronic medical records, faxing is slower than the internet, and it often requires follow-up telephone calls. Accordingly, CMS seeks comment on how to reduce or eliminate the use of fax technology. **Specifically, CMS seeks feedback on:**

- What programs, processes, workflows, or cases are faxes used for? How would replacing that process with an electronic data exchange add value, efficiency, or improve patient care? Are there processes (such as prior authorization) that should be prioritized first to reduce the reliance on fax technology? Has your organization implemented an electronic data exchange in an effort to reduce the reliance on the fax machine?

- 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?

- 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?

- To what extent can electronic and cloud-based fax technology bridge the gap between electronic transmission and traditional fax technology?

- What impact will the reduction of use of fax technology have on preparedness and response to disasters? How might organizations begin to reduce reliance on this technology, and mitigate these impacts?

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

As the use of value-based payment systems that emphasize whole person care have grown, interest in data on social risk factors has also increased. To date, however, data on social risk factors is difficult to collect because of different formats, can be duplicative as different providers collect similar information from beneficiaries, and they are difficult to integrate and utilize. CMS seeks input on the barriers to using industry standards for social risk data collection and on opportunities to increase the adoption of such standards. Specifically, CMS asks:

- 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)?

- 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?

- What mechanisms are currently used to exchange social risk and social needs data (EHRs, 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?

- 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?

IV. Incorporation by Reference

CMS describes the National Technology Transfer and Advancement Act of 1995 and the Office of Management and Budget (OMB) circular A-119 which require the use of technical standards developed or adopted by voluntary consensus standards bodies to carry out federal policy objectives wherever practical. In the proposed rule, the use of voluntary consensus standards is proposed. Such standards may be "incorporated by reference" and deemed published in the Federal Register so long as they are reasonably available to interested parties. To comply with the requirements that such standards must be reasonably available, CMS provides a description of the materials and their URLs. The following materials are incorporated by reference in this proposed rule:

- HL7 FHIR Da Vinci - Coverage Requirements Discovery (CRD) Implementation

Guide: Version STU 1.0.0. URL: http://hl7.org/fhir/us/davinci-crd/history.html.

Summary: The purpose of this IG is to define a workflow whereby payers can share coverage requirements with clinical systems at the time treatment decisions are made. CMS proposes this IG to support the DRLS API discussed in section II.C. The various CMS-regulated insurance and coverage products accepted by a given provider may have very different requirements for prior

authorization documentation. Providers who fail to adhere to payer requirements may find that costs for a given service are not covered or not completely covered. The outcome of this failure to conform to payer requirements can be increased out-of-pocket costs for patients, additional visits and changes in the preferred care plan, and increased burden. The information that may be shared using this IG includes updated coverage information, alternative preferred/first-line/lower-cost services/products, documents and rules related to coverage, forms and templates, indications of whether prior authorization is required.

- HL7 FHIR Da Vinci - Documentation Templates and Rules (DTR) Implementation

Guide: Version STU 1.0.0. URL: http://hl7.org/fhir/us/davinci-dtr/history.html.

Summary: This IG specifies how payer rules can be executed in a provider context to ensure that documentation requirements are met. The DTR IG is a companion to the CRD IG, which uses Clinical Decision Support (CDS) Hooks[5] to query payers to determine if there are documentation requirements for a proposed medication, procedure, or other service. When those requirements exist, CDS Hooks Cards will be returned with information about the requirements. This IG leverages the ability of CDS Hooks to link to a Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR[6] app to launch and execute payer rules. The IG describes the interactions between the SMART on FHIR app and the payer's IT system to retrieve the payer's documentation requirements, in the form of Clinical Quality Language (CQL)[7] and a FHIR Questionnaire resource, for use by the provider. This IG will also support the DRLS API discussed in section II.C. of this proposed rule.

- HL7 FHIR Da Vinci - PAS Implementation Guide: Version STU 1.0.0.

URL: http://hl7.org/fhir/us/davinci-pas/history.html.

Summary: The PAS IG uses the FHIR standard as the basis for assembling the information to substantiate the need for a particular treatment and submitting that information and the request for prior authorization to an intermediary end point. This IG also defines capabilities around the management of prior authorization requests, including checking the status of a previously submitted request, revising a previously submitted request, and cancelling a request. This IG would support the PAS API discussed in section II.C. of this proposed rule.

- HL7 FHIR Da Vinci - Payer Coverage Decision Exchange (PCDE) Implementation Guide: Version STU 1.0.0.

URL: http://www.hl7.org/fhir/us/davinci-pcde/history.cfml.

Summary: The IG defines standardized mechanisms for a patient or payer to enable a transfer of "current active treatments" with other relevant metadata and coverage-related information from a

[5] https://cds-hooks.org/.
[6] https://docs.smarthealthit.org/.
[7] https://cql.hl7.org/.

prior payer to a new payer. It also defines a standardized structure for organizing and encoding that information to ease its consumption by the new payer organization.

- HL7 FHIR Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide: Version STU 1.0.0.

URL: http://hl7.org/fhir/us/carin-bb/history.html.

Summary: This IG describes the CARIN for Blue Button Framework, providing a set of resources that payers can exchange with third parties to display to consumers via a FHIR-based API. This IG will help impacted payers share adjudicated claims and encounter data via the Patient Access API discussed in section II.A. of the proposed rule. It includes data elements and coding instructions each impacted payer can use to prepare and share the specified data.

- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide: Version STU 1.0.0.

URL: http://hl7.org/fhir/us/davinci-pdex/history.html.

Summary: This IG enables payers to create a member's health history from clinical resources based on FHIR Release 4 that can be exchanged with other payers, providers, and thirty-party applications. It supports patient-authorized exchange to a third-party application, such as the patient-requested prior authorization information via the Patient Access API discussed in section II.A. of the proposed rule. It will also support exchanging active prior authorization decisions between payers and providers via the Provider Access API discussed in section II.B. of the proposed rule.

- HL7 FHIR Da Vinci - Payer Data Exchange (PDex) US Drug Formulary Implementation Guide: Version STU 1.0.1.

URL: http://hl7.org/fhir/us/Davinci-drug-formulary/history.html.

Summary: This IG defines a FHIR interface to a health insurer's current drug formulary information for patient access. The primary use for this FHIR interface is to enable patients to understand the costs and alternatives for drugs that have been or can be prescribed, and to compare drug costs across different insurance plans. This IG would support the inclusion of current formulary and preferred drug list information via the Patient Access API as discussed in section II.A. of the proposed rule.

- HL7 FHIR Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide: Version STU 1.0.0.

URL: http://www.hl7.org/fhir/us/davinci-pdex-plan-net/history.cfml.

Summary: This IG is modeled off of the Validated Healthcare Directory Implementation Guide (VHDir), an international standard developed to support a conceptual, centralized, national

source of health care data that would be accessible to local directories and used across multiple use cases. VHDir as a basis for a centralized health care directory is in development. This PlanNet IG leverages the lessons learned and input provided throughout the extended VHDir development process, which has been informed by a large cross-section of stakeholders, and to address a narrower scope of health care directory needs. This IG specifically allows payers to share basic information about their own, local networks via a publicly-accessible API. At a minimum, this IG will support impacted payers sharing their providers' names, addresses, phone numbers, and specialties, which is the information required to be shared via the Provider Directory API discussed in section II.A. of the proposed rule.

V. Collection of Information

Under the Paperwork Reduction Act of 1995, CMS is required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval HHS identifies provisions in the proposed rule for which it estimates potential burden and that would require an information collection review and approval under the Paperwork Reduction Act of 1995.

Overall, CMS has estimated that there are 266 parent organizations that would be impacted by the rules, if finalized. They are comprised of plans, entities, issuers, and state programs likely to be impacted by the proposals. They include:

- 209 Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the FFEs;
- 56 states, territories, and U.S. commonwealths which operate FFS programs; and
- One state that operates its CHIP and Medicaid FFS programs separately.

Table 10 shows the total estimated burden across all impacted parent organizations is estimated to be $325.4 million in year 1; $311.5 million in year two, and $154.4 million for each subsequent year. Those cost estimates assume:

- The burden of certain proposals including the Patient Access API proposal and the provider directory API proposal are already accounted for in the maintenance costs estimated as part of the CMS Interoperability and Patient Access final rule. In addition, the burden of requiring the Privacy Policy Attestation is assumed to be part of the regular work of keeping the API up to date.
- The burden estimate for the proposed reporting of patient access API Metrics to CMS is presented in Table 2. First year implementation costs are estimated to be $14,645 per impacted organization. Aggregate costs across all 266 parent organizations are estimated to be $3.9 million. Ongoing maintenance could cost each organization about $2,905 per year for a total aggregated annual cost of $772,677.
- The Provider Access API proposal would require three major work phases: initial design, development and testing, and long-term support and maintenance. CMS summarizes its estimates of the costs of the first two phases in Table 3. One-time implementation efforts for the first two phases are estimated to cost $275,742 per organization with an aggregate burden across 266 parent organizations of $73.3 million. Ongoing maintenance costs are

expected to be about one-quarter of the one-time API costs or $575,285 per parent organization – for a total of $153 million across all 266 parent organizations.

- The Documentation Requirement Lookup Service API proposal would require three major work phases as well. CMS estimates one-time implementation costs for the first two phases of $984,181 per organization with aggregate costs across 266 parent organizations of $261.8 million.
- The costs of the Prior Authorization Support (PAS) API proposal are summarized in Table 5 and include one-time implementation costs of $936,400 per organization totaling $249 million across 266 parent organizations.
- The proposed amendment to the timelines for Medicaid and CHIP plans to send prior authorization decisions is expected to impact only 235 of the 266 parent organizations because it applies only to Medicaid and CHIP. The per entity costs are shown in Table 6 and sum to $946 per entity with a total burden of $222,404.
- The requirement for public reporting of prior authorization metrics would require first-year implementation costs of an estimated $28,685 per organization with total costs across all 266 parent organizations of $7.6 million. Ongoing maintenance would cost each organization on average $8,714 with aggregate costs of $2.3 million (in Table 7).
- The third-party application attestation for privacy is estimated (in Table 8) to cost each organization $28,686 for initial development and annual maintenance costs of $8,714. Total costs for all 266 parent organizations are estimated to be $7.6 million in year one and $2.3 million annually for maintenance.
- Establishing paper-to-payer API would require three work phases. For initial design and development, CMS estimates costs of $101,816 per organization for an aggregate across 266 parent organizations of $27.9 million (in Table 9). Ongoing maintenance costs are estimated to be $157,224 for each parent organization for an aggregate cost of $41.8 million.

VI. Regulatory Impact Statement

CMS examined the impact of the rules as required by Executive Order 12866 on Regulatory Planning and Review, the Regulatory Flexibility Act (RFA), the Unfunded Mandates Reform Act of 1995, Executive Order 13132, and Executive Order 13771.

Executive Order 12866 requires agencies to provide a regulatory impact analysis for all major rules with economically significant effects (of $100 million or more in any year). CMS estimates that the rule is economically significant and so has prepared a Regulatory Impact Analysis assessing the costs and benefits of the proposals.

The Regulatory Flexibility Act requires agencies to analyze whether a rule would have a significant impact on a substantial number of small businesses. CMS certifies that for impacted payers, the proposed rule does not have a significant economic impact on a significant number of small entities. CMS states that state Medicaid managed care plans and CHIP managed care entities have their costs covered through capitation payments from the federal government or through state payments; therefore, there would be no significant burden of the proposed provider access, DRLS, and PAS APIs. Few of the QHP issuers that would be impacted are small businesses.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. The proposed rule would not impose an unfunded mandate that would result in spending in a year in excess of the 2020 threshold of $156 million for a state, local or tribal government.

The estimated cost for review of the rule for each of the 266 parent organizations impacted is $1,253 for an aggregate total of $333,112.

Indirect Savings From Prior Authorization Proposals. CMS believes that an indirect impact of the proposed rule would be savings from reduced administrative work associated with prior authorization protocols. CMS provides a quantitative analysis of the potential cost savings resulting from reduced administrative work but because of limitations in the analysis and the uncertain assumptions used to develop the estimates, provides only illustrative savings. While CMS believes the savings could be significant, they are not included in the summary tables of the expected costs or benefits of the proposed rule.

CMS expects that an increasing percentage of providers will participate in electronic prior authorization such that by 2032, 25% of all providers will participate. The burden associated with the existing PA process is estimated to be $73,750 per physician practice per year. CMS estimates there to be between 218,187 to 450,000 of those practices.

Two provisions are expected to reduce prior authorization burden: (1) the proposed requirement to implement a DRLS API which is expected to result in a 25 percent reduction in hours spent identifying prior authorization rules and requirements; and (2) the proposed requirement that payers implement and maintain a PAS API which CMS estimates would result in a 50% reduction in the hours spent by clerical staff. CMS estimate savings of $21,648 per physician practice, and total savings that range from between $1.1 billion to $5.2 billion as shown in Table 16.

Total Costs of Proposed Rule. Overall, CMS estimates that the total costs of the proposed rule could range from $103.5 billion to $288 billion (in 2020 dollars, summarized in Table 21). As noted above, those costs do not incorporate the indirect savings that CMS has estimated range from $1.1 to $5.2 billion. It also allocates the costs to Medicaid and CHIP programs and to individual market plans in Table 19.

Table 20 proposes ways for payers to defray some of the costs of the proposed rule. For example, CMS proposes that states could request exemptions from some of the proposed API provisions and that QHPs could absorb the costs or request an exception because they are a small commercial QHP issuer on the FFE.

Alternatives Considered. CMS considered alternatives to the proposed provisions including:

- As an alternative to the update to the Patient Access API proposals, allowing patients and providers to upload patient data directly to a patient portal operated by a provider. Because patient portals are not sufficiently widespread and do not lend well to

interoperability, CMS declined to pursue this alternative. In addition, CMS considered alternative compliance dates.

- CMS considered alternative data types that could be exchanged via the proposed Provider Access API as well as including additional data elements. Its proposal aligned the requirements with those proposed for the Patient Access API.
- A phased approach was considered for proposals to implement DRLS API and PAS API, but CMS believes that it is less burdensome to require payers to populate these requirements for all items and services at the same time. CMS also considered requiring payers to post on a public website, items and services for which prior authorization is required, including their associated documentation rules as an interim step but determined that this would not provide any reduced burden on payers or providers. **CMS seeks comment on whether a payer website to provide additional transparency to prior authorization requirements and documentation would be beneficial in reducing burden.** CMS also considered a phased timeline for implementation as well as alternative timelines for prior authorization decisions.
- CMS considered more frequent reporting of prior authorization metrics but concluded that its proposal is sufficient.
- An enhanced Payer-to-Payer Data Exchange standard was considered as well as permitting a payer to share data without requiring the use of an API, but CMS determined it was most advantageous for payers to leverage an API for this enhanced data exchange. With respect to the data elements, CMS considered requiring only the exchange of clinical data, but determined that including claims and encounter data would allow for better care coordination and more efficient payer operations.