connect to them. To achieve widespread industry utilization of standards and maximize the benefits of a streamlined process, technology adoption by all involved stakeholders - including providers, payers, and EHR vendors - is essential. CMS should ensure that sufficient incentives are in place to promote provider adoption of electronic prior authorization and other required transactions contained herein. We urge CMS and ONC to establish specific requirements for EHR developers to include these functions in their technologies as part of the Certified Electronic Health Record Technology (CEHRT) program and for providers to use such technology as part of the Merit-based Incentive Payment System (MIPS) and information blocking regulations.

Resolve the infrastructure dependencies: The ONC Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (Information Blocking Rule), Interoperability, Transparency, and this Proposed Rules all establish policies focusing on the connection between each payer and each individual app developer and/or each individual provider. The ONC FHIR at Scale Taskforce (FAST) is actively working to identify common scalability approaches to speed adoption and avoid each stakeholder reinventing the wheel. Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek to industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.

***Clarify the interaction between the Proposed Rule and the IGs*:** The Proposed Rule appears to name certain IGs that do not cover the proposed exchanges, thus requiring IGs to be revised or newly created. Moreover, the IGs are still evolving with changes made to the CARIN Blue Button IG as late as December 20, 2020, that are not backward compatible. Standards and related IGs must be complete, tested, and stable before implementation of these provisions to avoid members having to “rip and replace" systems.

Protect patient privacy: While we appreciate CMS’s effort to provide a modicum of protection through the proposed privacy policy attestation, we do not believe it will be effective and could provide Americans with a false sense of security. In fact, it falls so short of what is required to protect privacy, that we believe it renders the Proposed Rule arbitrary. CMS should work with Congress to fill the gap in the national privacy framework to ensure health care data obtained by third-party apps is held to high privacy and security standards. At minimum, The Federal Trade Commission (FTC), in partnership with HHS, should establish a process whereby apps are vetted for the adequacy of their consumer disclosures, as well as the privacy and security of the information.

***Allow payers to include compliance costs as QIA in MLR*:** Developing and implementing these new technologies will require substantial resources for impacted payers. CMS should require states to allow Medicaid and CHIP managed care plans to treat these expenses as quality improving activity (QIA) and CMS should itself treat these expenses as QIA for QHP issuers, just as it did for ICD-10 compliance.

Our comments and recommendations regarding the Proposed Rule reflect AHIP's commitment to develop policy solutions that will support a more consumer-focused market, ensure access to meaningful, actionable information, and promote quality and affordability. AHIP and its members look forward to working with HHS to further refine these proposals and to determine an appropriate timeframe for implementing these provisions to advance greater interoperability between health insurance providers and both consumers and health care providers. If you have any questions, please reach out to Danielle Lloyd, senior vice president for private market innovations and quality initiatives at either dlloyd@ahip.org or 202-778-3246.

Sincerely,

I. Background and Summary of Provisions

A. Purpose

Timeline

AHIP and its members wholeheartedly support moving to a health care system where data flow seamlessly among stakeholders to achieve improved wellness and better health outcomes for all Americans while at the same time ensuring privacy and security. Furthermore, we embrace the next steps outlined by the Administration in this Proposed Rule to advance interoperability. However, the competing demands of the COVID-19 pandemic, the Interoperability and Patient Access Final Rule (Interoperability Rule)[2], and the Transparency in Coverage Rule (Transparency Rule) [3] paired with the lack of specified funding to underwrite the costs of implementation, and the fact that the standards and IGs on which this proposed rule is based are not yet fully mature requires AHIP and our member plans to oppose the implementation of the rule at this time and in its current form.

The requirements of the Proposed Rule, unlike the providers' move to the meaningful use of EHRs, creates an unfunded mandate on health insurance providers and state Medicaid and CHIP programs during a worldwide pandemic the end of which is not yet in sight. Health insurance providers have taken decisive action and made significant investments to educate consumers, scale telehealth, free up hospital capacity, facilitate vaccinations and more. The health care system continues to be stressed by the number of new cases and deaths. Introducing additional demands with no additional resources and limited time for implementation risks distracting from the crucial fight against the pandemic as we enter a key phase in defeating COVID-19 with the availability of vaccines.

Additionally, the pressure created by this Proposed Rule layers on top of not only the ongoing work to implement the Interoperability Rule but also the incredible demands placed on impacted payers' information technology staff and systems in shifting to the virtual care environment necessitated by the pandemic. Beyond the competing capacity demands, proceeding with this Proposed Rule without the benefit of evaluating experiences and lesson learned from the Interoperability Rule will increase the likelihood of missteps, need for rework, and duplicative costs to the federal government and health care system stakeholders. This is further exacerbated by the fact that the standards and IG that underpin this rule have not been fully developed. This work is necessary before HHS proceeds with further rulemaking.

The ONC Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (Information Blocking Rule)[4], as well as the Interoperability, Transparency, and Proposed Rules all also establish policies focusing on the connection between each payer and each individual app developer and/or each individual provider. The Office of the National Coordinator (ONC) for Health Information Technology (HIT) FHIR at Scale Taskforce (FAST),

[2] CMS 9115-P, 84 Fed. Reg. 7610 [March 4, 2019]
[3] CMS 9915-P, 84 Fed. Reg. 65464 [November 27, 2019
[4] RIN 0955-AA01, 84 Fed. Reg. 7424 [March 4, 2019]

including many AHIP members, is actively working to identify common scalability approaches to speed adoption and avoid each stakeholder reinventing the wheel. For implementation of these proposals to occur efficiently and at scale, further development, and industry adoption of the following ONC FAST solutions is required:

1. *Payer directory*—An application program interface (API) directory that can be referenced to know what a provider's or payer's API address is. FAST recommends funding and development of this directory. We also recommend CMS and ONC fund and complete this work before the APIs in the proposed rule are regulated.
2. *Security*—A security structure is required based on a tiered OAuth security specification to enable the scalable exchange of certificates within trust frameworks. Without agreement on this standard, the industry will not be able to implement at scale. The burden on physician and payer entities will be such that implementation will not be achievable. FAST is pursuing standards development with HL7 around this topic and we recommend ensuring this work is in place prior to making the APIs in the proposed rule mandatory.
3. *Identity resolution*—FAST recognizes there is not one single patient identifier accepted industry wide. Therefore, FAST identified approaches that should be adopted in cross-stakeholder API exchange. These approaches should be mature and tested prior to the APIs becoming mandatory.

The Proposed Rule also repeatedly fails to take account of existing regulatory obligations and contractual arrangements, generating conflicts and a lack of clarity regarding which rules control. For example, elements of the United States Core Data for Interoperability (USCDI) are included in the Patient Access, Provider Access, Prior Authorization Support (PAS), and Payer-to-Payer (P2P) APIs as well as the provider-required APIs in the ONC Information Blocking Rule, and yet it is not clear whether there is uniformity across the implementation guides (IGs). The precise conflicts are difficult to identify in the short time provided for comments and given it appears many of the IGs do not yet include the exchanges proposed by CMS.[5]

We believe that, as proposed, the rule rushes to create several requirements on payers that will fail to achieve the stated goals of improved quality and reduced provider burden as CMS and ONC on behalf of HHS failed to issue an integral component to ensuring the successful functioning of the proposed policies. While ONC issued a tandem Information Blocking Rule when CMS issued its Interoperability Rule, ONC merely lent its name to a section of this Proposed Rule. In doing so, ONC failed to propose parallel requirements for providers and Certified Electronic Health Record Technology (CEHRT) vendors. Interoperability, by definition, connects at least two parties. Without companion requirements, CMS is rushing to create requirements for impacted payers to be able to transmit information that cannot be received by the other party.

[5] *Portland Cement Ass'n v. EPA*, 665 F.3d 177, 187 (D.C. Cir. 2011) ("[A]n agency must have a similar obligation to acknowledge and account for a changed regulatory posture the agency creates—especially when the change impacts a contemporaneous and closely related rulemaking.").

Finally, the 17-day comment period from publication in the *Federal Register* (25 days from posting on CMS's website) is not only highly unusual but violates the Administrative Procedures Act (APA). When, as here, "substantial rule changes are proposed, a 30-day comment period is generally the shortest time period sufficient for interested persons to meaningfully review a proposed rule and provide informed comment." [6] The comment period here is barely half that, and encompasses two major holidays, all while health insurance providers are in the midst of addressing the ongoing response to the pandemic and the rollout of vaccines This alarmingly short comment period left stakeholders with 10 business days from publication to read, analyze, and prepare comments on an incredibly complex and technical rule. We are concerned that stakeholders were not given enough time to thoroughly consider the proposed policies and to develop recommended alternatives.

A comment period of at least 30 days is required for "significant" guidance documents, pursuant to Executive Order 13891 as well as HHS' Good Guidance Practices regulation issued on December 7, 2020. Under the Executive Order as well as the regulation, a "significant" guidance document is defined as one having an impact on the economy of $100 million or more.[7] The Good Guidance Practices regulation requires at least a 30-day notice and comment period for "significant" guidance documents.[8] CMS found that the Proposed Rule is an economically significant rule having an impact on the economy of at least $100 million.[9] Logic dictates that if HHS must afford even a significant piece of guidance at least a 30-day comment period, then a major rule must also be afforded at least 30 days for comment – but a 60-day comment period is necessary for economically significant rules such as this one.

Recent economically significant proposed regulations have been afforded 60 days' comment periods. For example, the CMS Interoperability Rule and the Information Blocking Rule both were issued with a 60-day comment period. (In fact, the comment deadline for the ONC rule was extended for another 30 days.[10] Another example is the Health Plan Transparency rule which HHS, along with the Departments of Labor and Treasury, determined to be economically significant and which also had a 60-day comment period. Finally, on the same day the Prior Authorization rule was released, a proposed Health Insurance Portability and Accountability Act (HIPAA) Privacy rule[11], also determined to be economically significant, included a 60-day comment period.

Despite multiple requests from the health care community for additional time to comment, the agency has provided no justification for the truncated comment period, and there is no reasonable basis for it. No statutory deadline compels action within days, and the agency has not identified any emergency need for the proposed changes. The agency has rightly not attempted to claim good cause for dispensing with notice and comment altogether, because providing an

[6] *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1117 (D.C. Cir. 2019).
[7] 45 C.F.R. §1.2, 85 Fed. Reg. at 78785 [December 7, 2020].
[8] 45 C.F.R. §1.3(b)(2)(ii) [85 Fed. Reg. at 78786].
[9] Prepublication version at p. 252.
[10] 84 Fed. Reg. 16834 [May 23, 2019]).
[11] CMS 4153-01-P

opportunity for public comment is neither impractical, unnecessary, nor contrary to the public interest.[12] The agency similarly cannot justify an unreasonably truncated comment deadline.

The only exigency that appears to exist is the impending transition in Administration, and the agency's decision to propose a rule so close to the transition cannot justify dispensing with a meaningful opportunity for public comment.[13] And, should the Administration attempt to finalize this rule before January 20, 2021, we assert that the government could not consider adequately stakeholder comments on an economically significant rule in just over two weeks. Indeed, a rush through the rulemaking process would suggest that the opportunity for comment was merely cover for an agency that had already made up its mind, contrary to the open mind the APA requires.[14]

Recommendations:

- *CMS should provide at least an additional 45-day comment period on the Proposed Rule.*
- *CMS should not finalize the proposals effective January 1, 2023 but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*
- *Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.*
- *CMS and ONC should promulgate comparable rules for providers and CEHRT vendors in tandem with further action on this rule, as we discuss throughout this letter.*
- *CMS and ONC on behalf of HHS should not seek to finalize this rule prior to the transition to the next Administration.*

Impacted Payers

CMS indicates its proposed new requirements to improve the electronic exchange of health care data and streamline processes related to prior authorization would only apply to the following payers: state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and qualified health plan (QHP) issuers on the Federally Facilitated Exchange (FFE), or "impacted payers."

CMS further indicates that the proposed new requirements would not apply to Medicare Advantage organizations at this time, although CMS would consider extending the proposed new requirements to Medicare Advantage organizations through future rulemaking. We appreciate and support CMS's decision to not propose any changes to the regulations governing Medicare

[12] *See* 5 U.S.C. § 553(b)(B); *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (The good cause exception "is to be narrowly construed and only reluctantly countenanced.").
[13] *Cf. Natural Res. Def. Council v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004) ("We cannot agree … that an emergency of [the agency's] own making can constitute good cause.").
[14] *See Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009) ("The opportunity for comment must be a meaningful opportunity, ... and ... in order to satisfy this requirement, an agency must also remain sufficiently open-minded.").

Advantage organizations. While Medicare Advantage plans are open to the idea of creating comparable technologies to further share information with consumers, providers and other payers, CMS should ensure a more methodical approach to seeking stakeholder input before applying similar policies to Medicare Advantage. This should include for example, listening sessions, requests for information, and/or Advance Notice of Proposed Rulemaking, so that the agency can consider all aspects of including these two areas.

However, we are concerned about the lack of clarity on whether all or a subset of Medicare Advantage plans that are dual-eligible Special Needs Plans (D-SNPs) could be subject to the rules due to their coordination with Medicaid plans. In addition, CMS does not address other arrangements that provide coordinated Medicare and Medicaid benefits, including Medicare-Medicaid Plan financial alignment demonstrations (MMPs) and Program of All-Inclusive Care for the Elderly (PACE) organizations. We believe that the proposed new requirements should not apply to any of these entities – Medicare Advantage plans (including D-SNPs), MMPs, and PACE organizations – until the APIs and prior authorization rules are fully tested and implemented and the country is no longer in the middle of a pandemic. This would help to minimize the risk of implementation challenges and costs diverting resources away from ongoing work of plans and their partners to coordinate benefits and address the unique challenges that COVID-19 creates for these high-risk populations.

At the same time, should CMS elect to finalize the rule, some impacted payers may prefer to implement these policies across all business lines. Due to the somewhat disjointed nature of the two rules, CMS should consider ways in which it can support voluntary adoption. Specifically, it should make sure that the underlying Medicare Advantage policies from the Interoperability Rule do not prevent impacted payers from voluntarily extending these policies and technologies to their Medicare Advantage plans and other products.

Regarding QHP issuers on the FFE, we appreciate that CMS' definition of QHPs excludes issuers offering only standalone dental plans (SADPs), Small Business Health Options Program Exchanges (FF–SHOPs), and QHPs offered in State-based Exchanges on the Federal Platform (SBE–FPs) from the proposed provisions of this rule. We agree with CMS that the proposed standards would be overly burdensome to both SADP and FF-SHOP issuers, as their current enrollment numbers and premium intake from QHP enrollment are unlikely to support the costs of the requirements that this Proposed Rule would impose. Additionally, we support SBE-FP states setting their own requirements for QHPs in their states.

Recommendation*:*

- *CMS should not finalize the effective date of January 1, 2023 for the provisions of this rule for any impacted payers. If, however, CMS proceeds should explicitly state in the final rule that the proposed new requirements also do not apply to MMPs, D-SNPs, and PACE organizations to mitigate confusion and avoid unintended consequences.*
- *CMS should specify in the final rule that state Medicaid programs may not unilaterally require dual eligible plans to implement the prior authorization and the API requirements for the Medicare components of their benefits.*

- *We support excluding QHPs offered in SBE-FP states from the requirements of this rule.*
- *We support the approach that both Stand Alone Dental Plans (SADP) and SHOP plans certified as QHPs on the FFE should be excluded from this regulation as they were for the Interoperability Rule. CMS should further clarify that the Proposed Rule's prior authorization provisions do not apply to dental insurers that provide coverage to Medicaid managed care enrollees.*
- *CMS should ensure that nothing would prevent impacted payers from voluntarily aligning with the policies in the Proposed Rule, when operationally feasible, for their other lines of business including Medicare Advantage and QHPs offered in the SBE-FP states.*

II. Provisions of the Proposed Rule

A. Patient Access API

1. Background

CMS is proposing new policies that build on the Interoperability Rule applicable to plans in federal programs as well as state Medicaid and CHIP FFS programs that requires the implementation of a Fast Healthcare Interoperability Resources (FHIR)-based Patient Access API to share certain clinical, formulary, and financial information with third-party application (app) developers at the request of an enrollee. Specifically, CMS is proposing to require impacted payers use certain IGs and add prior authorization decisions to the Patient Access API.

2. Enhancing the Patient Access API

AHIP recognizes the potential APIs give patients access to their health data, a valuable tool to help them take ownership of their health and healthcare. Some health insurance providers have already built patient access APIs and are actively promoting their use. However, we remain concerned about several provisions of the Patient Access API mandated in the Interoperability Rule and elaborated upon in the Proposed Rule. First, as we note above, the timeline for initial implementation is challenging, especially as health insurance providers are devoting substantial resources to the fight against COVID-19. Second, health insurance providers remain deeply concerned about the lack of certification for third-party apps and the risk to patient privacy they may pose. Finally, we wish to highlight the potential difficulties in implementing the prior authorization requirements of the API given the current state of the IG and the challenges that patients may face in understanding that information.

Recommendation:

- *CMS should not finalize the additional functionalities of the Patient Access API effective January 1, 2023 but rather reshape the provisions of the Proposed Rule into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*

a. Patient Access API IGs

First, CMS is proposing that impacted payers must use the IGs including the following proposed for adoption by ONC on behalf of HHS for the Patient Access API.

- 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 PDex US Drug Formulary IG: Version STU 1.0.1 to facilitate the exchange of current formulary information.

CMS wishes to codify these IGs in regulation as opposed to identifying them in sub regulatory guidance. We support a hybrid approach to timely standards updates. Specifically, the adoption of the HL7 FHIR standards and accompanying IGs in regulation, but with the allowance for voluntary use of updated standards or IGs between willing trading partners. AHIP recognizes the value of CMS providing additional structure and consistency to the APIs by naming specific IGs. At the same time, AHIP underscores the need to adopt updates to the technical standards as they evolve to keep up with innovation, especially those related to security. However, we caution CMS and ONC to ensure the development process of not only the standards but also the IGs are fully transparent and open to public comment. We emphasize that the IGs must be created through a process that all stakeholders can participate in, specifically through an ANSI accredited Standards Development Organization with a fair and transparent process that allows for public comment. CMS and ONC should then periodically seek comment on necessary updates to the regulations to establish a new floor for implementation.

While we support the use of the standards and IGs we are concerned about the maturity of the IGs for some of the proposed use cases. More time is needed for additional refinement and pilot testing before broad adoption of additional functionality. As detailed in the next section, we note there are no well-defined data standards or transaction sets for prior authorization (please see section b, Additional Information below for a detailed response). We also request guidance from CMS on how to account for prior authorization requests within the Patient Access API as the current standards and IGs do not account for such requests. While prior authorization status is defined in the Da Vinci Prior Authorization Support (PAS FHIR IG) (leveraging profiles based on the Claim FHIR IG) implementation could present difficulties. HL7 Da Vinci could add or update the guidance, but support for prior authorization status within the API will be challenging.

Recommendations:

- *We support CMS naming not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*
- *However, we request clarification on the mapping of specific API functionalities to specific IGs as it is not always clear in the Proposed Rule, some functionalities do not*

appear to be captured in the IGs, and some elements overlap in the IGs (e.g., USCDI CORE IG or the HL7 Da Vinci PDex).

- *Adopting or allowing the use of new versions of standards in regulations or guidance should follow their testing, implementation, evaluation, and refinement, and should occur only with clear and consistent public notice of schedule and public comment, as well as adequate time for implementation.*
- *CMS should ensure that all named IGs are created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that includes public comment.*

b. Additional Information

The Proposed Rule adds requirements to include as part of the already established Patient Access API information about prior authorization decisions. Payers will be required to include information about pending and active prior authorization decisions. Specifically, CMS is proposing to require payers to make available to patients information about:

1. active prior authorization decisions (and related clinical documentation and forms) for items and services,
2. pending prior authorization decisions, and
3. the status of the request (approved, denied or more information is needed).

The information would have to be made available through the Patient Access API conformant with the PDex IG no later than one business day after a provider initiates a prior authorization request or there is a change of status for the prior authorization. CMS is also requesting comment for possible future consideration on whether impacted payers should be required to include information about prescription drug and/or covered outpatient drug pending and active prior authorization decisions with the other items or services proposed via the Patient Access API as well as the Provider Access or the P2P APIs detailed below.

AHIP agrees that moving toward industry-wide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. However, it is not feasible to implement this solution at present. Current content or technical standards for prior authorization requests are not well-defined and the current Patient Access API IGs do not cover prior authorization requests. Additionally, this requirement may conflict with the existing requirements for sharing patients' information included in the USCDI as clinical documentation related to prior authorization requests would still be classified as clinical information. Finally, while we appreciate patients' need for timely information, the proposal to have prior authorization requests and status available within one business day of the request being made is not operationally possible. A more feasible option would be to require availability within one day of receipt of the 278 request which is the X12 transaction required for the prior authorization request. Additionally, such information would have limited value for patients as the payer would have limited information to share about the status of the prior authorization request. For example, with delegated requests, a payer will often

receive an update only on the final disposition, as opposed to more frequent updates on changes in status. As a result, there would likely be no information to share for several days which could cause the patient undue confusion.

AHIP agrees with the potential value of including information about prescription drug and/or covered outpatient drug pending an active prior authorization decision with the other items or services proposed via the Patient Access API. However, more information is necessary about the scope of prescription drugs as some prescription drugs fall within a plan's medical benefits and others within the pharmacy benefits and the two sets of benefits are often administered using two different processes with different operational implications. We also request more detail on potential scenarios such as how to address drugs that are prescribed but never picked up by the enrollee. This can occur, for example, when a prescription is automatically filled with electronic prescribing, but the patient decides they do not want to take the drug or cannot afford it. Including this information may also cause challenges due to the volume of potential data.

The number of prescription drug-related authorizations is far greater than authorizations for medical services and could present greater challenges to facilitating access to this information via the API. If CMS does choose to require this information in the future, we suggest limiting the scope to a single region or market as a pilot test. Additionally, we would recommend limiting the prior authorization history to one year to make the amount of available data more manageable.

If HHS chooses to finalize this proposal, CMS should revise several of the requirements to make implementation more feasible. First, CMS should clarify what precise information must be available on pending prior authorization decisions. Will the date of the request, the nature of the request, and that it is pending be sufficient? Also, any new requirements must align with other existing requirements. CMS proposes to require that the pending and active authorizations include "the related clinical documentation and forms." The supporting documentation is often in the form of lengthy and cumbersome PDF documents. These unstructured data are not easy to parse for relevant elements and convert to FHIR resources. In fact, CMS has taken the position that the clinical data required to be part of the Patient Access API in the Interoperability Rule does not have to be converted to FHIR resources if obtained in file formats like PDF and JPEG. Additionally, we have concerns about CMS requiring the units and services used to date as part of the API because such data would need to be updated in real time as claims come in to be accurate and useful to those accessing the data through the API. It would be time-consuming and labor intensive to implement the required mapping, tracking, and updating of prior authorization data each time a unit or service approved is consumed within one business day. Finally, CMS must ensure that the technical standards and related IGs reflect the relevant content and policies to allow for the seamless transfer of such information.

Recommendations:

- *CMS should not finalize the proposal to add prior authorization data to the Patient Access API effective January 1, 2023 but rather reshape the provisions of the Proposed*

Rule into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.

- *CMS should support the development of content and technical standards for prior authorization decisions that can then be incorporated into the appropriate IGs for testing before inclusion in the regulations.*
- *CMS should withdraw the requirement that the pending and active authorizations include "the related clinical documentation and forms."*
- *CMS should require only the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date.*

c. Privacy Policy Attestation

CMS is proposing to require that impacted payers request a privacy policy attestation from third-party app developers when their app requests to connect to the payer's Patient Access API. Specifically, CMS is proposing to require impacted payers to establish, implement, and maintain a process for third-party app developers to attest to certain privacy policy provisions prior to retrieving data.

We appreciate CMS' work to address potential privacy concerns regarding the release of patient health information to third party applications. The privacy and security of member data is a major concern for health insurance providers. However, the policy to require attestations from the developer when the app engages the API may create undue burden on payers and confusion and delay for patients trying to access their data without providing meaningful protections. It is an unreasonable expectation for CMS to require payers to step in between the member and the app. Impacted payers have no contractual or legal relationship with the app developer and cannot act to rectify non-adherence to the attestation other than referral to the Federal Trade Commission (FTC) given the payer cannot deny the request on its own volition. Moreover, the attestation process could be antithetical to the Interoperability Rule, which emphasized that patients must have freedom to choose apps and payers should not interfere with that decision. Yet, having an impacted payer create an attestation process for apps may give members a false sense of security and the impression that the responsibility for privacy lies with the impacted payer should something go wrong.

AHIP is concerned about the potential for bad actors to exploit data gained via the APIs and the potential consequences for patients and their families. An attestation is unlikely to stop a truly bad actor and does not provide the FTC with the necessary evidence to take legal action against a developer. As an alternative to this proposal, we believe CMS should work with Congress to fill the gap in the national privacy framework to ensure that health care data obtained by third-party apps are held to a high privacy and security standard. There is no reason the member's data obtained by an app should be held to a lower standard than when that same information is held by a health insurance provider.

Besides the practical and policy issues with the attestation provision, it falls far short of what is needed to protect health care data and thereby renders the proposed rule arbitrary for failure to

meaningfully address an "important aspect of the problem."[15] As CMS acknowledges, the security and privacy of patients' health care information is paramount in this context, and health insurance providers are legally obligated to protect that information. Yet the unenforceable app developers' attestation is the only "safeguard" in the Proposed Rule against improper use or disclosure of that data. And, given the proposed rule's disclosure default if a patient does not respond within an extremely short period of time to notice of non-attestation, an impacted payer may be required to disclose protected health information to a third party (en route to the patient) without even that slim degree of protection. This does not meet Congress's intent, expressed in HIPAA and other statutes, that health care information be provided the highest level of protection. To the extent CMS believes that it can do no more on its own because it lacks direct authority over app developers, that does not preclude the obvious alternative of working with the FTC to develop an integrated regulatory framework that provides enforceable protections for health care information. Or, to the extent CMS believes that existing statutory authorities are insufficient to require third-party app developers to protect health care information, the only answer consonant with congressional intent to protect this information is to postpone the rule until the requisite statutory authority is secured. It is no answer—or, a wholly arbitrary one—to simply require the information to be disclosed to third parties with no meaningful protection.

Recommendations:

- *We urge HHS to work with Congress to extend HIPAA or similar robust consumer protections in connection with third party apps.*
- *The Federal Trade Commission (FTC), in partnership with HHS, should establish a process whereby apps are vetted for the adequacy of the consumer disclosures, as well as the privacy and security of the information once it is no longer governed by HIPAA and secondary uses are permitted. To the extent that payers are engaged in the attestation process, they should be granted a hold harmless to protect against any undue risk introduced by bad actors.*
- *CMS should make clear in the final rule that impacted payers receiving attestations do not have oversight or ongoing management requirements with regards to privacy attestations. No liability should attach to impacted payers that rely on the attestations provided by third-party app developers.*
- *HHS should name a national, industry body to manage a hub for third-party app developers to register and attest for their apps.*

Member Education

All stakeholders, including payers, should play a role in patient education regarding data sharing. At the same time, we believe the HHS in collaboration with the FTC should take the lead in making consumers aware of the risks and implications of granting data sharing access to third-party apps and how to lodge complaints specific to the aps. Given CMS's experience

[15] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).

implementing the Medicare Blue Button 2.0 initiative as well as the associated consumer education campaign, it is well situated to leverage lessons learned and apply them to this broader effort including consumer education. It should be made clear to consumers that HIPAA protections do not apply and that the healthcare or health insurance provider furnishing the data on their behalf are not responsible for the privacy or security of the data obtained by apps or sold for secondary uses. CMS could also use its authority to share the information it obtains from its vetting process for Medicare data to establish ratings of the apps on its website.

Recommendation:

- *CMS could also use its authority to share the information it obtains from its vetting process for Medicare data to establish ratings of the apps on its website.*

Timeline

CMS is proposing that impacted payers must request the third-party app developer's attestation at the time the third-party app engages the API. Under this proposal, the payer must inform the patient within 24 hours of requesting the attestation from the app developer of the status of the attestation – positive, negative, or no response, with a clear explanation of what each message means. The patient would then have 24 hours to respond to this information. CMS notes that if the patient does not respond or the patient indicates they would like their information to be made available regardless, the payer would be obligated to make the data available via the API.

AHIP recognizes the need to balance the burden of additional regulations with the benefit of providing more information to patients. As outlined in the Proposed Rule, the process would be resource intensive given the 24-hour time frame to inform the patient of the status of the attestation. Moreover, email may not be a feasible option in all circumstances due to limitations imposed by state laws and first-class mail would not meet the required timeframe outlined in the Proposed Rule. We are particularly concerned about the 24-hour deadline given to patients to respond before data is shared with the third-party app, regardless of the response to the privacy attestation. This could have unintended consequences for patients if they are not focused on receiving and responding to the notification from their health plan. We also ask CMS to reconsider the proposal to consider a non-response within 24 hours as consent to data sharing. If CMS does choose to finalize the attestation process where patients can override the fact that a third-party app developer did not attest to the privacy policies (whether passively or actively), it should also consider a process for the member to revoke that permission later. Given our concerns about the 24-hour deadline for patients, we would ask that this policy require payers to stop the data feed as soon as reasonably possible.

Recommendations:

- *CMS should not finalize the proposal to accept a lack of response from the patient as affirmation of acceptance of the privacy attestation.*
- *We request clarification and further guidance on the process CMS intends for impacted payers to follow and ensure that it is straightforward and simplistic.*

Process
CMS did not propose specific methods for how impacted payers could meet this requirement. However, it is also unclear if payers would be required to obtain an attestation each time the app engages the API or if a previously received attestation would be sufficient for a certain period. To create a more efficient process, impacted payers should be able to request the attestation when they register the app. Should something change, the onus would be on the developer to advise the impacted payer. AHIP also requests clarification on whether it would be permissible for an impacted payer to maintain and publish publicly a list of which third-party apps had and had not provided attestations.

Recommendations:

- *If CMS requires impacted payers to collect the privacy attestation, it should be a one-time occurrence and not be required every time the patient accesses the data.*
- *CMS should develop a policy to allow payers to stop information sharing with the third-party app as soon as reasonably possible should the patient notify the payer of a request to opt-out.*

d. Patient Access API Metrics

CMS is proposing to require the reporting of quarterly metrics about patient use of the Patient Access API. Specifically, CMS is proposing that payers report quarterly the total number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app and the number of unique patients whose data are transferred via the Patient Access API to a patient designated third-party app more than once.

CMS is seeking comment on whether to consider requiring these data be reported to CMS at the contract level for those payers that have multiple plans administered under a single contract or permit Medicaid managed care plans, CHIP managed care entities, or QHP issuers on the FFE to aggregate data for the same plan type to higher levels (such as the payer level or all plans of the same type in a program). In addition, CMS seeks comment on whether it would be more appropriate to report annually rather than quarterly.

AHIP does not support the implementation of these metrics as the information generated would not be a meaningful reflection of the value of the impact payer's API. We ask CMS to continue to emphasize the goals of the "Patients over Paperwork" initiative and continue to prioritize the reporting of metrics that are truly meaningful to improving patient care.

While impacted payers could perhaps influence the number of unique visits through member outreach and education, the results of the metric assessing data transfer to a third-party app more than once reflect the quality and user experience of the third-party application, not the impacted payer. Moreover, these metrics would be influenced by regional, demographic, and member-specific factors outside the health insurance provider's control such as availability of broadband services, smart phone adoption, socioeconomic status, and a member's desire to adopt and use new technology.

If CMS chooses to finalize this proposal, annual reporting would be less burdensome on the impacted payers and would be less influenced by potential seasonal variations in the data (e.g., newly enrolled members being more motivated to request data). Additionally, if CMS finalizes this proposal, these metrics should be aligned with other administrative items impacted payers are required to report to meet federal and state requirements. A single set of common data requirements would minimize the burden of reporting such data.

As an alternative to this proposal, we suggest CMS work with FTC to have third-party app developers report these metrics as the developers are a more reasonable accountable entity to these metrics and influencing their results is within the developers' locus of control.

Recommendations:

- *CMS should not implement these reporting metrics. If CMS chooses to finalize this proposal, we urge HHS to require annual rather than quarterly information.*
- *We request additional transparency around to whom these metrics will be reported to and for what purpose.*
- *We also request clarification on what is meant by "'the number of unique patients whose data are transferred more than once." Given the configuration of a typical FHIR dialogue, a request could be counted in different ways and results could become skewed.*

e. Patient Access API Revisions

While the HL7 DaVinci PDex IG is a good foundation, the standard itself is not in a state that would lend confidence to meeting the January 1, 2023 compliance deadline. Many differences in the requirements for this API exist (e.g., not requiring FHIR Bulk Data Access (Flat FHIR) IG ((bulk data specs)), which will drive added implementation burdens because the Patient Access API implementations cannot be as easily reused. Bulk data transfer will require industry consensus on the mechanisms to specify and maintain aligned patient panels. For example, there should be an agreed to convention for naming the population groups (which are different for each payer to provider relationship). Without a consensus, there will be variations across payers, causing abrasion with providers within value-based arrangements. Patient Access has a well-defined set of standards and expectations for scaling the implementations (i.e., via Open Authorization (OAuth) and SMART-app-launch specifications). However, ONC FAST specification outlines infrastructure requirements that are needed for scaling provider to payer interactions, which are in-scope when moving beyond a single payer, such as Medicare FFS. These would include solutions for endpoint discovery, security, and identity resolution**.**

Recommendation:

- *Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.*

f. Provider Directory API Implementation Guide

CMS is proposing to require that the Provider Directory API be conformant with the HL7 FHIR Da Vinci PDex Plan Net IG: Version 1.0.0. CMS notes that because QHP issuers on the FFE are already required to make provider directory information available in a specified, machine-readable format, the Provider Directory API proposal does not include QHP issuers.

We support the adoption of the HL7 FHIR standards and accompanying IGs. AHIP also supports allowing ONC to update the standards as they are identified through a transparent sub regulatory process that allows for public comment. AHIP generally supports implementing new technical standards as they are adopted and approved to keep up with innovation, especially those related to security. AHIP also recognizes the value of CMS providing additional structure and consistency to the APIs by naming specific IGs. However, CMS should ensure the development process of not only the standards but also the IGs are fully transparent and offer public comment on their proceedings by stakeholders.

We also reiterate our earlier comments on the challenges in creating and maintaining provider directories. Health insurance providers are committed to providing accurate information in provider directories and work continuously to improve the quality of the directories made available to our members. Health insurance providers are subject to several federal requirements to keep provider directories up to date. In addition, at least 39 states also impose state-specific provider directory requirements. For example, QHPs in the FFE have been subject to requirements to provide machine-readable provider directories since 2016 and have learned many lessons about the operational and technical barriers to enabling the consumer experience envisioned in the proposed rule as it regards provider directories. Experience with QHP machine readable files highlighted two formidable barriers that present major challenges to achieving seamless electronic access to accurate provider network participation status for a specific consumer or patient: (1) providers do not consistently provide updates; and (2) there is no single source-of-truth for provider information that can be leveraged to support tools that rely on machine-readable provider directories or apps obtaining provider information through an API. If these barriers are not addressed, making provider directory information available through APIs as proposed in the rule will not enable successful digital curation and the seamless electronic access CMS seeks to achieve.

Recommendations:

- *We support CMS naming not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*
- *CMS should ensure that all named IGs are created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that includes public comment.*
- *Adopting or allowing the use of new versions of standards in regulations or guidance should follow their testing, implementation, evaluation, and refinement, and should occur*

only with clear and consistent public notice of schedule and public comment, as well as adequate time for implementation.

- *To ensure success of the Provider Directory API, CMS should establish a public-private partnership including impacted payers to develop a federally-operated national data repository with bi-directional access by providers and payers that can be leveraged as a source of truth for provider data accuracy and completeness given inconsistencies in reporting requirements across states and programs.*

B. Provider Access APIs

1. Background

CMS is proposing to require impacted payers to build and maintain a new Provider Access API to share claims and encounter data (not including cost data), a sub-set of clinical data as defined in the USCDI version 1, and pending and active prior authorization decisions for both individual patient requests and groups of patients starting January 1, 2023. CMS is also proposing to require that the Provider Access API comply with the same technical standards, API documentation requirements, and discontinuation and denial of access requirements as apply to the Patient Access API.

We appreciate that CMS took into consideration AHIP's previous comments that it would not be appropriate to share confidential cost information through APIs. While this may be a long-term goal within the Provider Access API to facilitate physician consideration of costs in suggested care plans, our members are not able to do this in a sufficiently sophisticated way at present. Thus, sharing costs could have a stifling effect on competition and is not necessary for the notion of sharing clinical information at this time.

AHIP recognizes the need to streamline data sharing to reduce provider burden and improve care coordination and patient safety. Health insurance providers today share copious amounts of data with their network providers to improve the care provided to our members. The exchange occurs through different mechanisms depending on the impacted payer. For some providers, this is in the form of dashboards reflecting the results of their care compared to peers obtained through a web-based portal. In other cases, particularly those providers with value-based contracts, the health insurance providers share large-scale raw claims data files. We appreciate that CMS is proposing to harmonize the exchange through a FHIR-enabled Provider Access API. However, the return on this substantial investment by impacted payers as well as the federal and state governments can only be achieved if there is comparable and substantial uptake by providers.

CMS and ONC must establish policies to encourage vendors to build and providers to adopt the systems to exchange information through the Provider Access API as well as support the use of its added functionality. CMS should look to lessons learned from the introduction of electronic prescribing and its inclusion in the Medicare Modernization Act of 2003. At that time, pharmacies and pharmacy benefit managers (PBMs) invested in creating an infrastructure to support electronic prescribing recognizing that it would improve the safety and efficiency of the prescribing process. This included building the necessary technical standards and technology

infrastructure and implementing Medicare payment policies and state requirements to offer incentives followed by requirements for providers to use electronic prescribing which ultimately led to widespread adoption of electronic prescribing and its resulting safety and efficiency benefits. Use of MIPS and ONC CEHRT are potential levers CMS could explore to promote provider adoption of the PAS API. Technology adoption by all involved stakeholders, including providers, payers, and EHR vendors, is necessary to achieve widespread industry utilization of standards. Without adoption and use by the entire ecosystem, patients will not benefit from this hurried one-sided requirement of impacted payers.

If HHS chooses to finalize this proposal, CMS should revise several of the requirements to make implementation more feasible. First, CMS should clarify what precise information must be available on pending prior authorization decisions. Additionally, we have concerns about CMS requiring the units and services used to date as part of the API because such data would need to be updated in real time as claims come in to be accurate and useful to those accessing the data through the API. I Finally, CMS must ensure that the technical standards and related IGs reflect the relevant content and policies to allow for the seamless transfer of such information.

Recommendations:

- *CMS should provide at least an additional 45-day comment period on the Proposed Rule.*
- *CMS should not finalize the proposals effective January 1, 2023 but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*
- *We urge ONC to establish specific requirements for EHR developers to include these functions in their technologies as part of the CEHRT program, and for both providers and EHR developers as part of the Information Blocking regulations.*
- *We also urge CMS to include incentives for providers within the Advancing Care Information Performance category within the MIPS program to use the Provider Access API in their workflows in parallel with the requirement on payers to create and maintain the API.*
- *CMS should support the development of content and technical standards that can then be incorporated into the appropriate IGs for testing before inclusion in the regulations.*
- *CMS should withdraw the requirement that the pending and active authorizations include "the related clinical documentation and forms."*
- *CMS should require only the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date.*

3. Proposed Requirements for Payers: Provider Access API for Individual Patient Information Access

CMS notes that providers would be allowed to request the claims and encounter data for patients to whom they provide services for treatment purposes. Additionally, CMS specifies that the Provider Access API is intended to connect directly with a provider through their EHR or other practice management system so that it may be incorporated in their workflow. This API is not

intended to serve members though a third-party app for use on a mobile device but rather to facilitate the exchange of data to providers through an EHR or other practice management system.

CMS is proposing that the Provider Access API should be consistent with the APIs finalized in the Interoperability Rule and utilize HL7 FHIR version 4.0.1 to facilitate the exchange of current patient data from payers to providers. CMS is also proposing to require that the Provider Access API comply with the same technical standards, API documentation requirements, and discontinuation and denial of access requirements as apply to the Patient Access API.

As noted above in the Patient Access API section, AHIP recognizes the value of CMS providing additional structure to the APIs by naming specific IGs. We support the adoption of these standards to provide greater clarity and certainty in the development of the required APIs. AHIP also supports allowing ONC to update standards as they are identified. AHIP supports implementing new technical standards as they are approved, tested, and adopted especially those related to security. However, we are concerned about the maturity of the current IGs which have not been broadly tested for these purposes. We recommend CMS consider additional pilot testing before mandating broad adoption or delay timelines for implementation of the APIs until performance of the IGs is better understood, as well as any unintended consequences.

AHIP notes there are no well-defined data standards or transaction sets for prior authorization. While prior authorization status is defined in the HL7 Da Vinci Prior Authorization Support (PAS FHIR Implementation Guide (IG) (leveraging profiles based on the Claim FHIR), implementation could present difficulties. HL7 Da Vinci could add or update the guidance but support for PA status within the API may be challenging. We suggest that these elements be fully defined in the PAS FHIR IG and fully tested prior to the implementation of the prior authorization requirements included in this proposed rule. AHIP supports the standardization of the IGs but there is a need to ensure the development process is open to all stakeholders. IGs must be created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that does not require a fee to comment or participate.

AHIP appreciates that payers could require out of network providers to demonstrate a care relationship with the patient prior to transferring data. However, we request guidance on permissible processes for user authentication to ensure requests are truly coming from a provider. We note that CMS anticipates providers would connect with an EHR or other practice management system. However, we are concerned that this expectation could change as the ecosystem evolves and third-party apps for providers could be developed where user authentication could become more challenging.

Recommendations:

- *CMS should provide at least an additional 45-day comment period on the Proposed Rule.*
- *CMS should not finalize the proposals effective January 1, 2023 but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*

- *Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.*
- *We support CMS naming not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*
- *However, we request clarification on the mapping of specific API functionalities to specific IGs as it is not always clear in the Proposed Rule, some functionalities such as prior authorization do not appear to be captured in the IGs, and some elements overlap in the IGs (e.g., USCDI CORE IG or the HL7 Da Vinci PDex).*
- *Adopting or allowing the use of new versions of standards in regulations or guidance should follow their testing, implementation, evaluation, and refinement, and should occur only with clear and consistent public notice of schedule and public comment, as well as adequate time for implementation.*
- *CMS should ensure that all named IGs are created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that includes public comment.*

2. Proposed Requirements for Payers: Bulk Data Provider Access API

Impacted payers would be required to make patient data available to providers both on an individual patient basis and for one or more patients at once using a bulk specification, as permitted by applicable law, so that providers could use data on their patients for such purposes of facilitating treatment. Specifically, impacted payers would be required to implement and maintain a standards-based Provider Access API using the bulk data specs at 45 CFR 170.215(a)(4) to allow providers to receive the same information as indicated above for the individual patient request Provider Access API -- their patients' claims and encounter data (not including cost information such as provider remittances and enrollee cost-sharing); clinical data as defined in the USCDI version 1, where such clinical data are maintained; and formulary data or preferred drug list data, where applicable; as well as information on pending and active prior authorization decisions. CMS is inviting public comment on the benefits of having the Provider Access API available with and without the use of the bulk data specs.

AHIP notes potential challenges to implementing the bulk data specifications. First, it is unclear how the necessary patient consent (or opt-in as the case may be) would be collected in bulk data transactions. Additionally, the bulk data specifications may not be the most efficient system and is redundant, to a certain extent, to the "individual patient use case." Moreover, a bulk data transfer would require a standard for sharing and maintaining the populations to which the providers are entitled to share data. This new function would require a new IG, that in turn, would require testing at scale for industry adoption.

We also have concerns about the utility of the information returned by the bulk access API. For patients with several health conditions, sending all claims data to the provider's EHR could result in a significant amount of information being sent. This information may not be usable depending on how the EHR filters and consolidates the data. Moreover, providers may feel

obligated to make requests through the API before every appointment to ensure up to date information. However, this could result in multiple copies of data being sent and significant amounts of data being exchanged. CMS should work with providers to make them aware of tools that could facilitate use of the API such as the CARIN search parameters.

Recommendations:

- *CMS should not finalize the effective date of January 1, 2023 for the Provider Access API using the bulk data specs until at least January 1, 2024 and no sooner than a new IG can be developed and tested for tracking provider attribution and access privileges.*
- *We recommend that CMS work with impacted payers, EHR developers, and providers to develop a content standard for the Provider Access API to ensure it returns actionable information that providers can use as part of their care.*
- *We urge ONC to establish specific requirements for EHR developers to include these functions in their technologies as part of the CEHRT program, and for both providers and EHR developers as part of the Information Blocking regulations.*
- *We also urge CMS to include incentives for providers within the Advancing Care Information Performance category within the MIPS program to use the Provider Access API in their workflows in parallel with the requirement on payers to create and maintain the API.*

1. Additional Proposed Requirements for the Provider Access APIs

CMS is proposing that the requirements for the Provider Access APIs largely align with the Patient Access API. However, there are additional proposed requirements specific to the Provider Access API proposals related to attribution, patient opt-in, and provider resources.

a. Attribution

For patient attribution, CMS is proposing that each payer establish, implement, and maintain for itself, a process to facilitate generating each provider's current patient roster to enable this proposed payer-to-provider data sharing via the Provider Access API. CMS is also proposing that impacted payers would be permitted to put a process in place for patients to opt-in to use the Provider Access API for data sharing between their payer and their providers.

Attribution is a notoriously challenging aspect of health care measurement. Often, a patient's identification of 'their doctor' may not match the results generated by algorithmic approaches. Moreover, most attribution processes currently are geared toward identifying a singular accountable primary care physician within value-based arrangements. It is not clear if CMS intends to the attribution process to identify a single clinician, a practice, or even multiple physicians (e.g., specialists). Attribution approaches in this instance must balance the required amount of data for care coordination with concerns about patient privacy and adhering to HIPAA.

The Proposed Rule incorporates by reference the technical specifications for the exchange of data through the Provider Access API, but it does not specify the security controls required for

the provider to gain access. Per above, it is not clear if access is to be granted to an individual clinician or the group through which s/he) may bill (e.g., Tax Identification Number). Moreover, the process outlined in the Proposed Rule seems to contradict the process flow outlined in the Interoperability Rule which emphasized the role of health information networks (HINs) and the use of health information exchanges (HIEs) as the avenue for providers to exchange and retrieve data. The Trusted Exchange Framework and Common Agreement (TEFCA) rule, that has not yet been issued, was intended to be a foundational component of exchange between payers and providers. Without this, impacted payers will have to establish individualized rules diminishing the value of interoperability.

While we appreciate that patients may choose to see a provider who is not part of their payer's network and those providers could also benefit from the data available via the API, attribution and security validation may be particularly difficult in this circumstance. Payers may not be able to generate an accurate attribution list that includes these providers if not all their services are through an electronic data exchange (e.g., patient pays up front and later seeks reimbursement). Moreover, without a contract and any specific information on the provider, it will be difficult to determine validate the provider's eligibility to access the data. And, whether the requesting entity is a third-party app developer rather than the physician. In the proposed rule, CMS suggests payers could confirm upcoming visits for new patients, but this may cause patients undue concerns about payer interference in their healthcare. Moreover, this policy could result in delays in patients accessing care as providers may be unwilling to schedule patients without a complete record.

Recommendations

- *We request clarification and guidance on the intended level of attribution for access to a member's data.*
- *We also request clarification on how payers should address attribution for out-of-network providers.*
- *CMS should provide clarification on the required security controls for the Provider Access API.*

b. Opt-In

CMS is also proposing that impacted payers would be permitted to put a process in place for patients to opt-in to use of the Provider Access API for data sharing between their payer and their providers.

AHIP appreciates CMS's efforts to protect patient privacy and allow patients greater control of their data. However, we do not believe such a process is necessary under HIPAA if attribution and data sharing is confined to those clinicians fitting the existing treatment, payment, and operations definition. Additionally, the regulations under 42 CFR Part 2 will be imminently aligning with HIPAA per new law. Moreover, there are existing processes at the state levels that differ in terms of whether there is an opt-in or an opt-out. CMS setting a specific process here could be operationally challenging. Does CMS anticipate that information on whether a patient

has opted in/out of data sharing at the state level will then be included in enrollment files shared by the state with the payers? On what level does CMS anticipate members will be able to opt-in or out of data sharing? Will this be high level data (e.g., opt-in/out on data sharing for claims, prior authorization, or clinical data) or would it be at a more granular level (underlying conditions, specific medication, etc.)? Finally, how does CMS anticipate information on whether a member has opted into data sharing flowing to impacted payers?

Recommendations

- *CMS should ensure any patient consent process for provider access to data is operationally feasible and deferential to existing state processes.*

c. Provider Resources

CMS is also proposing that payers make educational resources available to providers that describe how a provider can request patient data using the payer's Provider Access APIs in nontechnical, simple, and easy-to-understand language.

AHIP agrees that impacted payers should notify providers in their networks to ensure understanding of the availability of this resource. However, CMS neither defines the term "educational resources" nor the distribution method. Impacted payers will not be able to provide much guidance on how providers could use the Provider Access API as the exchange is intended to be with the EHR vendor to integrate the data into the provider's workflow. We believe sufficient information will be provided through the information on the impacted payer's website around the registration process for access to the API for EHRs to connect with and obtain the data.

Moreover, education is not likely to be the primary barrier to provider adoption of the API. As noted above, we are concerned that without meaningful incentives (positive or negative), many providers will be hesitant to adopt this new technology, especially if ONC does not require EHR vendors to adopt the same standards and implementation is not seamless for the provider.

Recommendations:

- *CMS should clarify that the educational responsibilities of impacted payers entails payers notifying in-network providers via their usual communication methods of the availability of members' information and where the providers' vendors can register to access the data on the payers website.*

d. Extensions and Exceptions for Medicaid and CHIP FFS.

CMS is proposing a process through which states may seek an extension of and, in specific circumstances, an exemption from, the Provider Access API requirements if they are unable to implement these API requirements.

We support CMS's proposal to provide an extensions or exemptions process for the state Medicaid agencies operating FFS programs. States are and will continue to experience severe repercussions because of COVID-19 including impacts on their economies, unemployment rates and fluctuating Medicaid enrollment. However, we note that states that leverage private sector health plans to deliver Medicaid are also under considerable financial pressures resulting in significant reductions in health plan reimbursements already experienced in multiple states. For this reason, Medicaid managed care plans will similarly be challenged to take on this added cost during the COVID-19-created financial downturn and should be afforded the same latitude for exceptions as states.

Recommendation:

- *We agree with CMS that there is a need for extensions and exemptions for Medicaid and CHIP FFS programs for the Provider Access API.*
- *CMS should also clarify that a state can request a second extension, if circumstances warrant, in the following year rather than seeking an exemption from the start.*
- *CMS should proactively monitor for systemic impacts on states that would limit their ability to implement such policies, such as a termination of the enhanced FMAP, and alter effective dates accordingly.*
- *We further urge CMS to create an exception and an exemption process across all APIs for both states and Medicaid managed care plans including dental insurers that provide coverage to Medicaid managed care enrollees.*

e. Exception for QHP issuers

CMS proposes an exception that could apply to small issuers, issuers who are only in the individual or small group market, financially vulnerable issuers, or new entrants to the FFEs who demonstrate that deploying standards based API technology consistent with the required interoperability standards would pose a significant barrier to the issuer's ability to provide coverage to consumers, and not certifying the issuer's QHP would result in consumers having few or no plan options in certain areas.

We also support CMS's proposal to provide an exception process for the Provider Access API for QHPs like the one provided under the Patient Access API in the Interoperability Rule. However, as noted above, we believe impacted payers of all types may have difficulty implementing these extensive requirements.

Recommendation:

- *We agree with CMS that there is a need for exceptions for certain QHP issuers for the Provider Access API.*
- *We urge CMS to establish both an exception and an exemption process across all APIs for all impacted payers.*

C. Reducing the Burden of Prior Authorization through APIs

3. Proposed Requirement for Payers: Documentation Requirement Lookup Service (DRLS) API

CMS is proposing to require payers to implement and maintain a FHIR-enabled Document Requirement Lookup Service (DRLS) API that can be integrated with a provider's EHR and allow providers to look up prior authorization requirements for each payer. CMS is proposing to require that the DRLS API comply with the same technical standards, API documentation requirements, and discontinuation and denial of access requirements that apply to the Patient Access API. Additionally, the DRLS API is to be conformant with the:

- HL7 FHIR Da Vinci Coverage Requirements Discovery (CRD) IG: Version STU 1.0.0, and
- HL7 FHIR Da Vinci Documentation Templates and Rules (DTR): Version STU 1.0.0 IG.

In the Proposed Rule preamble, CMS indicates that it believes a payer requirement will increase provider demand for the functionality and seeks comment on what they can do to encourage development of these functions in EHR systems and incentivize providers to use payer DRLS APIs in their workflows.

AHIP appreciates CMS's attention to the issue of making prior authorization requirements readily accessible to providers as part of their workflows. Currently, prior authorization requirements are accessible to providers and posted on public facing websites, along with supporting documentation. Making prior authorization requirements electronically accessible to providers at the point-of-care in EHRs has the potential to improve process efficiencies, reduce time to treatment, and result in fewer prior authorization requests because providers will have the coverage information they need when making treatment decisions. However, technology adoption by all involved stakeholders, including providers, payers, and EHR vendors, is key to achieving widespread industry utilization of standard electronic prior authorization processes and the associated benefits.

We have previously commented in the context of CMS's pilot of a DRLS API in Medicare FFS that such a requirement should be phased in to ensure the use of fully tested standards, such as FHIR, and ensure that EHR systems have developed and delivered the functional capabilities in a manner that is integrated with provider workflows to support the DRLS. We appreciate that CMS is proposing that the DRLS API be FHIR-enabled but are concerned that the significant efforts that would be required to make a DRLS API available would not result in substantial uptake by providers in use of the DLRS without specific incentives, such as through the MIPS Program and ONC CEHRT requirements. Given the substantial time and effort it will take to build the DRLS API and populate it with prior authorization data and conditional requirements, it is essential that the benefits of the investment be realized through provider adoption.

In addition, there is not an established standard for all the functions required within the DRLS API, hindering the ability of impacted payers from scaling a solution. The DRLS API will

require provider-to-payer API interactions that go beyond a single payer, such as Medicare FFS. Thus, scaling infrastructure requirements are also needed for directory, security, and identity resolution (akin to needs of a Health Information Network). As a starting point, we recommend definition of standards and pilots of industry-wide solutions for the three infrastructure needs so that participants can test, correct, and scale the technology to achieve the common goal of efficient interoperability to achieve better health outcomes. Below we provide further detail on our concerns.

- *Identity Management*—An identity resolution solution with industry consensus is required (e.g., via a common intermediary), as there could be a significant burden on health IT developer solutions and on provider group clinical operations without it. For example, the rule as proposed may require the combination of revenue cycle management (RCM) and EHR module data for payer coverage and membership information.
- *Document Templates and Rules*-- HL7 Da-Vinci Coverage Requirements Discovery (CRD) and Document Templates and Rules (DTR), rely on HL7 Clinical Quality Language (CQL) and FHIR questionnaires to codify documentation templates. This is currently a draft set of technologies, with some complexity:
    - HL7 CQL specification and the system engines do not currently perform reliably - they rely on codification of clinical policy documents (which are written/communicated in natural language). This will be a burden for payers to implement, with scarce resources available to support them.
    - A simpler, less prescriptive IG generically based on the Substitutable Medical Apps Reusable Technologies (SMART) SMART-on-FHIR and Clinical Decision Support CDS-hooks specification underpinnings should be considered.
    - Alternative prior authorization approaches, like 'gold-carding' or automated-background-approvals could be restricted by the prescriptive DTR IG as well.
- *Data and Code Sets*— A structured approach to prior authorization documentation may require data and code sets beyond USCDI/US-Core. The HL7 "Uniform Structure and Coding of Elements for Prior Authorization" project is just starting on this discovery work.

Recommendation:

- *CMS should provide at least an additional 45-day comment period on the Proposed Rule.*
- *CMS should not finalize the DRLS API proposals effective January 1, 2023 but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*
- *Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.*
- *We support CMS naming not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*

- *CMS should ensure that all named IGs are created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that includes public comment.*
- *Adopting or allowing the use of new versions of standards in regulations or guidance should follow their testing, implementation, evaluation, and refinement, and should occur only with clear and consistent public notice of schedule and public comment, as well as adequate time for implementation.*
- *We urge ONC to establish specific requirements for EHR developers to include these functions in their technologies as part of the CEHRT program, and for both providers and EHR developers as part of the Information Blocking regulations.*
- *We also urge CMS to include incentives for providers within the Advancing Care Information Performance category within the MIPS program to use the DRLS API in their workflows in parallel with the requirement on payers to create and maintain the API.*
- *CMS should support the FAST standards development efforts with HL7 and ensure that authorization standards are aligned prior to implementing the DRLS API.*
- *A pilot approach to implementing the DRLS would allow for the maturity and scaling of this project.*

4. Proposed Requirement for Payers: Implementation of a Prior Authorization Support (PAS) API

CMS is proposing to require payers to implement and maintain a FHIR-enabled electronic PAS API that can send and receive prior authorization requests and responses electronically. The PAS API is to be conformant with the HL7 FHIR Da Vinci PAS IG. Like the DLRS, CMS believes a payer requirement will increase demand for the functionality and motivate EHR vendors to invest in integrating a PAS API directly into providers' workflows and seeks comments on what they can to encourage this transition. CMS is also proposing to use the PAS API to promote consistency in communicating prior authorization decisions, including whether the payer approves (and for how long), denies, or requests more information. Payers would also be required to provide the specific reason for a denial of a prior authorization request.

We agree that moving toward industry-wide adoption of electronic prior authorization transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. For the past year, AHIP has been coordinating a demonstration project with two health information technology companies and multiple plans and providers to evaluate the impact of automating various aspects of the prior authorization process. The results of our demonstration will provide valuable information on the impact on patients, providers, and plans of using electronic approaches to prior authorization that are standards-based, scalable, payer agnostic, and as integrated as possible with practice workflow. We have engaged an independent, not-for-profit research institute to perform an evaluation of the impact of electronic prior authorization. We anticipate having the results of the independent evaluation in early 2021.

While the evaluation is not final, AHIP interprets initial findings to suggest that the level of provider adoption of a new technology solution – that is, the extent to which a provider uses the electronic prior authorization functionality in their clinical workflow for most of their patients – influences their experience with the solution in a positive way. Their positive experiences include reduced burden, authorization information and processes that are easier to understand, and faster time to treatment for patients. The results also show that one-third of these providers use the specific electronic prior authorization technology solutions in the study for most of their patients.

We appreciate that CMS is proposing that the PAS API be FHIR-enabled. However, we are concerned that the significant efforts and investments that would be needed by impacted payers to make a PAS API available would not result in substantial uptake by providers in adoption or use of the PAS API without specific incentives to encourage adoption and use of the functionality, such as through the MIPS program and ONC CEHRT requirements. Technology adoption by all involved stakeholders, including providers, payers, and EHR vendors, is necessary to achieve widespread industry utilization of standard electronic prior authorization processes. Without adoption and use by the entire ecosystem, patients will not benefit from this one-sided requirement on impacted payers.

CMS should look to lessons learned from the introduction of electronic prescribing and its inclusion in the Medicare Modernization Act of 2003. At that time, pharmacies and PBMs invested in creating an infrastructure to support electronic prescribing recognizing that it would improve the safety and efficiency of the prescribing process. This included building the necessary technical standards and technology infrastructure, implementing Medicare payment policies and state requirements to offer incentives, and then requirements for providers to use electronic prescribing. These efforts ultimately led to widespread adoption of electronic prescribing and its resulting safety and efficiency benefits over several years with significant collaboration across participants in the network. Use of the MIPS and ONC CEHRT are potential levers CMS could explore to promote provider adoption of the PAS API.

Another obstacle to effective implementation of the PAS API is that it is dependent on codified and relevant clinical information being present in the EHR at the time of ordering to successfully adjudicate the prior authorization request. While EHRs and providers are improving in their ability to codify the medical record, significant variation remains. Non-structured data in the EHR as well as inconsistent formatting leads to potential errors, which can create patient safety concerns. As a result, there are significant challenges to adjudicating prior authorization requests through API interfaces without additional clinical data.

Similarly, we are also concerned about the proposed framework requiring a FHIR-based API for prior authorization workflow and data flow processes while the HIPAA-defined X12 278 prior authorization transaction standard requirement remains in force. This FHIR “wrap around” framework would require the prior authorization request from a provider to go from FHIR (via a payer’s PAS API) to the currently mandated 278 transaction (via a clearinghouse or intermediary) and then on the back end, from the 278 transaction back to FHIR to respond to the

requesting provider. Because the 278 transaction does not allow for all of the clinical information needed for plans to make a prior authorization decision in many cases, there has been low adoption of the transaction. Continuing to enable FHIR through a "lowest common denominator" 278 transaction will not result in desired outcomes because stakeholders are required to translate FHIR to 278, exchange, and then translate from 278 back to FHIR. Payer and provider burden is likely to actually increase when attempting to align FHIR and 278 transaction independently. Instead, CMS should consider the use of a FHIR-based API end-to-end solution between providers and payers, without having to convert back and forth into the 278 transaction. In the meantime, CMS should use enforcement discretion and permit impacted payers to use end-to-end FHIR-based solutions without having to convert to a 278 transaction.

In addition to the need for incentives for EHR developers and providers, this dependency on additional clinical information speaks to the need for national standards for the electronic exchange of clinical documents to promote greater use of the 278 transaction. A recent report released by the Council for Affordable Quality Healthcare (CAQH) highlighted the significantly higher adoption of electronic prior authorization by PBMs as compared to medical plans and notes the availability of an electronic standard that supports electronic communication of pharmacy-related clinical documentation.[16] With only 20 percent of attachments associated with medical claims and prior authorization being transmitted electronically,[17] the lack of attachment standards for medical information is considered to be a primary cause of this inconsistency in practice. In fact, the National Committee on Vital and Health Statistics (NCVHS) recently reiterated its recommendation to HHS that national standards for the electronic exchange of clinical documents be adopted.[18] Developing and implementing new standards are necessary to fully automate electronic prior authorizations and would greatly reduce the administrative burdens associated with prior authorization. Such standards are currently being developed by HL7 DaVinci but are not finalized. Lastly, a final and fully tested implementation guide is needed for this API.

Recommendation:

- *CMS should provide at least an additional 45-day comment period on the Proposed Rule.*
- *CMS should not finalize the PAS API proposals effective January 1, 2023 but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*
- *Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.*

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[16] 2019 CAQH Pharmacy Services Index. December 2020. https://www.caqh.org/sites/default/files/explorations/index/index-pharmacy-brief.pdf

[17] 2019 CAQH Index. Conducting Electronic Business Transactions: Why Greater Harmonization Across the Industry is Needed. https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf

[18] National Committee on Vital and Health Statistics. Letter to Secretary Azar on Recommendations for Proposed Operating Rules for Prior Authorization and Connectivity for HIPAA Transactions. November 23, 2020. https://ncvhs.hhs.gov/wp-content/uploads/2020/11/NCVHS-recommendations-on-Operating-Rules-FINAL-11-24-2020-508.pdf

- *We support CMS naming not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*
- *CMS should ensure that all named IGs are created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that includes public comment.*
- *However, we request clarification on the mapping of specific API functionalities to specific IGs as it is not always clear in the Proposed Rule, some functionalities do not appear to be captured in the IGs, and some elements overlap in the IGs (e.g., USCDI CORE IG or the HL7 Da Vinci PDex).*
- *CMS should support the development of prior authorization content and technical standards that can then be incorporated into the appropriate IGs for testing before inclusion in the regulations.*
- *Adopting or allowing the use of new versions of standards in regulations or guidance should follow their testing, implementation, evaluation, and refinement, and should occur only with clear and consistent public notice of schedule and public comment, as well as adequate time for implementation.*
- *We urge ONC to establish specific requirements for EHR developers to include these functions in their technologies as part of the CEHRT program, and for both providers and EHR developers as part of the Information Blocking regulations.*
- *We also urge CMS to include incentives for providers within the Advancing Care Information Performance category within the MIPS program to use the PAS APIs in their workflows in parallel with the requirement on payers to create and maintain the PAS APIs.*
- *We urge CMS and ONC to further develop FHIR-based standards to replace the 278 transaction, the 278i attachment that has yet to be finalized, and the 275 transaction optional standards. At the same time, HHS should establish enforcement discretion for impacted payers to allow end-to-end FHIR transactions for this use case without converting back and forth from the X12 standards.*
- *If CMS finalizes a hybrid approach with both HIPAA transaction sets and a FHIR-enabled "wrap around" for prior authorization, we urge CMS and ONC to conduct a pilot with the SDO and impacted payers to ensure the intended functionality before broad adoption.*

a. Requirement to Provide a Reason for Denial

The Proposed Rule requires impacted payers to include a specific reason for a denial when denying a prior authorization request, regardless of the method used to send the prior authorization decision, to facilitate better communication and understanding between the provider and payer. Currently, CMS requires that beneficiaries and providers receive communications on decisions made for prior authorizations, which include a denial rationale as well as information on what would be necessary to approve the request. This denial rationale is provided in the written communication sent to the beneficiary and provider.

CMS has defined a set of "reason for denial of prior authorization" codes (CMS Review Reason Codes), yet the extent to which those codes are used by impacted payers is unclear. Thus, it will be necessary for the industry to establish reason for denial codes, beyond those currently in place from CMS, to be used under this requirement. Because of this, it is unclear how this could be converted to a FHIR resource at this time.

Recommendations:

- *We request clarification on how the requirement in the Proposed Rule would be different from the current notification provided today, whether this section is specific to the electronic communication through the PAS API, and whether this would supplement or replace the written notice currently required.*
- *If CMS finalizes its proposal, we recommend the creation of a baseline taxonomy standard to promote consistency in electronic communications of the reason for a prior authorization denial.*

5. Seeking Comment on Prohibiting Post-service Claim Denials for Items and Services Approved Under Prior Authorization

CMS is requesting input on issues that could inform a future proposal to prohibit payers from denying claims for covered items and services for which a prior authorization has been approved. They noted that this issue came up during listening sessions with stakeholders and are interested in learning how new policies could help improve the process and prevent patients from receiving unexpected bills.

We appreciate CMS's attention to the issue of patients receiving unexpected bills. While retrospective denials following prior authorization approvals are uncommon, there are several reasons why such a denial would be warranted that should be considered in any future proposal on this issue. These include:

- *Eligibility*. An item or service received prior authorization, but when the service was delivered, the patient was no longer eligible (e.g., not covered).
- *Expired*. An item or service was given prior authorization for a specific length of time (typically 60-90 days), but by the time the service was delivered, the authorization had expired.
- *Additional Services*. A specific item or service was given prior authorization, but additional services were delivered that were not pre-approved.
- *Site of Care/Level of Care*. An item or service was given prior authorization for provision/delivery at a specific site of care (e.g., physician office or outpatient) but the item or service was provided/delivered in other setting (e.g., inpatient).
- *Duplicate Services*. An item or service was given prior authorization, delivered, and the claim was paid, but the same item or service was subsequently ordered by another provider within a certain timeframe, which would flag a discrepancy for a duplicate service (e.g., patient has MRI ordered by a primary care physician and then is referred to a specialist who orders another within a short time period).

- *Fraudulent Prior Authorization*. An item or service was given prior authorization and provided/delivered, but retrospective review determined the prior authorization was obtained fraudulently.

Moreover, states may have varying Medicaid and insurance regulations for QHPs that govern if and when post-service claim denials are appropriate. Introducing federal requirements could cause confusion and operational burden for impacted stakeholders give preexisting state guidance. CMS should ensure that states retain flexibility to craft programs best suited for their populations, and as such, should defer to them on the appropriate guidance.

Recommendation:

- *To limit confusion and operational burden, CMS should continue to defer to states to create and enforce regulations regarding post-service claims denials.*
- *We urge CMS to consider these program integrity, patient safety, and quality of care reasons for a retrospective denial of an item or service that has been given prior authorization in any development of a future proposal on this topic. Failure to do so could lead to an increase in improper payments and program costs.*

6. Requirements for Prior Authorization Decision Timeframes and Communications

CMS proposes to modify the timeframes for making prior authorization decisions (except for QHP issuers). Currently, decisions are required to be made and communicated as expeditiously as the enrollee's condition requires and within state-established timeframes that may not exceed 14 calendar days following receipt of the request for standard decisions, and 72 hours for expedited decisions when the provider indicates that following the standard timeframe could seriously jeopardize the enrollee's life, health, or ability to attain, maintain, or regain maximum function. CMS is proposing to maintain the current timeframe of 72 hours for expedited decisions but shorten the timeframe for standard decisions from 14 days to 7 days.

Without a critical mass of providers positioned to link to the API, achieving shorter prior authorization turnaround timeframes will be challenging. The reduction in the timeframe for making standard prior authorization decisions could also potentially result in even greater inconsistency across markets and products, risking confusion for providers and potentially patients. For example, Medicare Advantage requires standard prior authorization decisions as expeditiously as the enrollee's condition requires, but no later than 14 calendar days from when the request is received, while a 15-day timeframe is in place for QHP issuers and plans that undergo private accreditation through either the National Committee for Quality Assurance (NCQA) or URAC. Reduction in timeframes could also result in an increase in the number of timeframe extensions if insufficient time is provided for a quality review. Moreover, State Medicaid plans today have a myriad of different decision/communication timeframes that payers must meet. Each state Medicaid entity sets their own decision/communication timeframe and documents such timeframes within the contract document with each contracted Medicaid payer.

According to AHIP's industry survey[19], one of the primary reasons a request for prior authorization is initially denied is because the plan did not receive the necessary documentation to support the prior authorization request, despite plans' significant efforts to make information on required documentation readily transparent and available to providers. Therefore, it is essential that any timeframe requirement be linked to the impacted payer's receipt of the information necessary to make the prior authorization determination.

Recommendations:

- *We recommend that the current timeframes - as expeditiously as the enrollee's condition requires, with a maximum of 14 calendar days for standard prior authorization decisions and 72 hours for expedited prior authorization decisions - be maintained.*
- *We urge CMS to clarify that the timeframes for making both standard and expedited prior authorization decisions are tied to the impacted payer's receipt of the required documentation necessary to support the provider's prior authorization request.*
- *If CMS finalizes its proposal, we request definitive clarification as to whether the proposed change will either honor, or supersede all current State Medicaid contractual requirements and become the standard Medicaid managed care plan requirement for all states.*
- *To encourage provider uptake of electronic prior authorization and reduce the administrative burden associated with the shorter turn-around times, if CMS finalizes its proposal, the shorter timeframes should only apply to electronic prior authorization requests.*

7. Proposed Extensions, Exemptions and Exceptions for Medicaid and CHIP and QHP issuers

a. Extensions and Exemptions for Medicaid and CHIP FFS Programs

CMS is proposing a process through which states may seek an extension of and, in specific circumstances, an exemption from, the PAS API requirements if they are unable to implement these API requirements.

We support CMS's proposal to provide an extensions or exemptions process for the state FFS agencies. States are and will continue to experience severe economic repercussions because of COVID-19 including impacts on their economies, unemployment rates and fluctuating Medicaid enrollment. However, we note that all impacted payers, not just states, will have to go through a budgetary process, select vendors, and potentially hire staff.

Recommendation:

- *We agree with CMS that there is a need for extensions and exemptions for Medicaid and CHIP FFS programs for the PAS API.*
- *CMS should also clarify that a state can request a second extension, if circumstances warrant, in the following year rather than seeking an exemption from the start.*

[19] https://www.ahip.org/wp-content/uploads/Prior_Authorization_Survey_Infographic.pdf

- *CMS should proactively monitor for systemic impacts of these requirements on states, such as the continuing surge in COVID-19 cases, the impact of the economic downturn on Medicaid enrollment, and the post-public health emergency termination of the enhanced FMAP and alter effective dates accordingly.*
- *We further urge CMS to create an exception and an exemption process across all APIs for all impacted payers.*

b. Exceptions for QHP Issuers

CMS proposes an exception that could apply to small issuers, issuers who are only in the individual or small group market, financially vulnerable issuers, or new entrants to the FFEs who demonstrate that deploying standards based API technology consistent with the required interoperability standards would pose a significant barrier to the issuer's ability to provide coverage to consumers, and not certifying the issuer's QHP or QHPs would result in consumers having few or no plan options in certain areas.

We also support CMS's proposal to provide an exception process for the PAS API for QHPs like the one provided under the Patient Access API in the Interoperability Rule API. However, as noted above, we believe impacted payers of all types may have difficulty implementing these extensive requirements.

Recommendation:

- *We agree with CMS that there is a need for exceptions for certain QHP issuers to the PAS API.*
- *We urge CMS to establish both an exception and an exemption process across all APIs for all impacted payers.*

8. Public Reporting of Prior Authorization Metrics

CMS is proposing that payers publicly report prior authorization information annually, with metrics to include:

- a list of all items and services that require prior authorization;
- the percentage of standard prior authorization requests approved, denied, and approved after appeal;
- the percentage of prior authorization requests for which the timeframe was extended and the request was approved;
- the percentage of expedited prior authorization requests approved; and
- the average and median time between submission of a standard prior authorization request and the payer decision.

These metrics would be reported separately for items and services and reporting would begin March 31, 2023 based on 2022 data.

Our member plans support transparency of meaningful information on the prior authorization process for both providers and enrollees and routinely make available the list of items and

services that require prior authorization. However, we do not believe the additional proposed metrics would provide useful information to consumers, given that approval and denial percentages do not provide insight into the reasons why prior authorization requests were denied. Not only do the proposed metrics fail to provide an accurate benchmark of quality, but we are greatly concerned that such information, without context, could be misinterpreted and misleading and could undermine the value of prior authorization as an important tool to ensure safe and clinically appropriate treatments.

As mentioned above, one of the primary reasons a request for prior authorization is initially denied is because the plan did not receive the necessary clinical information to support the prior authorization request from the ordering provider, despite plans' significant efforts to make information on required clinical documentation readily transparent and available to providers. For example, in many cases, pertinent clinical history, physical examination findings, laboratory results, or previous imaging reports are necessary to determine whether a requested service is clinically appropriate. Without this information, a request may be initially determined to be inappropriate until additional information is eventually submitted by the provider during a peer-to-peer discussion, reconsideration, or appeal with an eventual authorization. With this newly supplied clinical information, many initial decisions marked as "inappropriate" are reversed, yet these details would not be captured by the proposed metrics.

Another common reason for an initial denial is that the requested procedure or medication is not clinically appropriate for the patient based on the medical literature or clinical guidelines. Unfortunately, significant levels of waste and low-value care persist, with one survey reporting that 65 percent of physicians believe that at least 15-30 percent of medical care is unnecessary.[20] The fact that a provider is requesting an item or service that is not evidence-based is also important information that would not be captured by the proposed reporting requirements. In short, not including the reasons for denials with the denial percentages provides an incomplete picture of relevant prior authorization information.

CMS has previously acknowledged the value of prior authorization in addressing fraud, waste, and abuse and Medicare FFS has implemented several prior authorization demonstration programs for specific services that have been recommended for extension and expansion by the GAO.[21] Most recently, CMS has added new prior authorization requirements in Medicare FFS for certain outpatient services[22] as well expanded its non-emergent ambulance prior authorization demonstration program.[23] Also, in response to an OIG report concerning Medicare Advantage plans, CMS acknowledged that "[i[f a claim is denied and that denial is overturned on appeal, the original denial may still have been appropriate, particularly when the denial was due to lack of supporting documentation and the documentation is provided during the appeal."[24]

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[20] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181970
[21] https://www.gao.gov/assets/700/691381.pdf
[22] https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0
[23] https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide
[24] https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf

Lastly, we are concerned that a requirement to report these metrics separately for items and services will be administratively challenging without offering commensurate value to consumers and providers.

Recommendations:

- *Given the uncertain value of these metrics to consumers, we recommend that the requirement to publicly report the identified metrics be deleted from the rule.*
- *If CMS finalizes its proposal, we recommend that CMS consider the following modifications:*
    - *(1) include information on the reasons for the prior authorization denials;*
    - *(2) allow for the reporting of information on items and services on a combined basis rather than separately;*
    - *(3) report information to CMS (similarly to Medicaid Managed Care Organization (MCO) reporting to states), rather than publicly; and*
    - *(4) allow for a longer claim run-out time, such as a June posting date rather than a March posting date, to accommodate an annual reporting requirement.*

9. Request for Comments on "Gold Carding" Programs for Prior Authorization

CMS is requesting input on issues that could inform a future proposal to implement "gold carding" or similar programs to relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. They noted that this issue came up during listening sessions with stakeholders and are interested in learning how new policies could offer additional efficiencies in the prior authorization process. They also point to a similar approach CMS is using in the Medicare FFS Review Choice Demonstration for Home Health Services,[25] under which home health agencies in demonstration states that select certain review choice options and have a review affirmation rate or claim approval rate of 90 percent or greater over 6 months are given the option to continue in the pre-claim review program or choose a selective post-payment review or "spot check" review process.

We appreciate CMS' interest in "gold carding" programs. Encouraging the use of programs that differentiate the application of prior authorization based on consistent provider performance on quality measures and adherence to evidence-based guidelines or other contractual agreements (e.g., risk-sharing arrangements) over time can be helpful in targeting prior authorization requirements where they are needed most and reducing the administrative burden on high-performing health care providers. In fact, in previous comments to CMS, we requested that CMS reaffirm that selective application of prior authorization based on a provider's adherence to evidence, performance, or participation in risk-based contracts is permissible in the Medicare Advantage program. Additionally, encouraging the use of such programs was one of the five

[25] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-%20Programs/Medicare-FFS-Compliance-Programs/Review-Choice-Demonstration/Review-Choice-Demonstration-for-%20Home-Health-Services.html

areas identified in a Consensus Statement on Improving the Prior Authorization Process[26] that AHIP developed in collaboration with the American Hospital Association, American Medical Association, American Pharmacists Association, BlueCross BlueShield Association, and Medical Group Management Association.

While gold carding programs offer opportunities to improve efficiencies, there are several challenges to their widespread. First, criteria for inclusion in these programs must be very well defined and communicated. Examples of criteria for selective application of prior authorization may include, for example, ordering/prescribing patterns that align with evidence-based guidelines and a track record of high prior authorization approval rates.

Second, it is important to note that gold carding is not a blanket exemption from all prior authorization indefinitely. These programs may be targeted to specific services, provider performance can be regularly reviewed post-service, and gold carding privileges can be revisited if necessary. These guardrails are necessary given that high performance may slip once a provider is gold carded. Health plans have, however, observed that performance is more likely to remain high in circumstances where the provider is accepting some form of risk and has an incentive to manage utilization/maintain quality.

A third challenge is that provider performance and adherence to evidence-based guidelines tends to be inconsistent, making it difficult to gold card a provider or clinic across the board. For example, a provider may have high approval rates relative to the ordering of some services/treatments, but not all. Likewise, some providers within a clinic or group practice may order some services/treatments consistent with evidence-based guidelines but others in the same clinic or group practice may not.

Fourth, there may be pressure on plans to gold card both in and out-of-network providers. Plans generally believe that gold carding should be reserved only for in-network providers. By making gold carding criteria publicly available and requiring plans to gold card regardless of network status, CMS would be creating an inappropriate incentive for providers to stay out-of-network enriching providers while reducing choice of providers whose performance is monitored by the health plan and raising costs for consumers.

Finally, it is unclear how this requirement would interact with both federal and state anti-discrimination laws applicable to physicians, employers and health insurers. States, for example, may require insurers to make the benefit provided under a plan available uniformly to all similarly situated individuals. [27] We strongly recommend further review of laws to understand whether CMS's gold carding program could be construed as unlawful discrimination given that it may result in inconsistent treatment of patients, employees, and insureds.

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[26] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf

[27] N.H. Code Admin. R. Ins 1907.05, ARSD 20:06:46:06 and 50 Ill. Adm. Code 2001.9.

Recommendation:

- *CMS should consider these challenges in exploring any potential future policies on "gold carding" programs, maintain the stated intent not to be overly prescriptive in defining requirements in future rulemaking, and provide payers with the necessary flexibility to customize such programs based on the specific needs and characteristics of their provider partners and the consumers they both serve.*

10. Additional Requests for Comment

Individuals with Chronic Conditions and Plan Changes

Based on discussions during their listening sessions, CMS is seeking comments on whether there are opportunities to improve the prior authorization process for individuals with chronic medical conditions by implementing restrictions on requirements for repeat prior authorizations for items and services for chronic conditions or offering longer term authorizations. Additionally, CMS is seeking comments on whether a prior authorization decision should follow a patient when they change from one plan to another and under what circumstances.

We agree that continuity of patient care is vitally important for patients with chronic conditions on established therapy as well as those undergoing an active course of treatment who switch health plans. Multiple standards addressing timeliness, continuity of care, and appeals are currently in place, including state and federal law and private accreditation standards. For example, the most recent COVID-19 relief package includes continuity of care provisions for patients with complex care needs during a 90-day transition period when a provider changes network status. We recognize that CMS wishes to consider additional efforts to minimize burdens and patient care disruptions associated with prior authorization in these instances. In the Industry Consensus Statement on Improving the Prior Authorization Process,[28] continuity of care under these circumstances was identified as a key priority. Specifically, stakeholders supported continuity of care for patients on appropriate, chronic, stable therapy through minimizing repetitive prior authorization requirements. Similarly, stakeholders supported continuity of care during a transition period for patients undergoing an active course of treatment when there is a treatment coverage change or change of health plan that may disrupt their current course of treatment.

Recommendations:

- *CMS should consider existing standards on continuity of care in exploring any policy changes.*
- *Similar to other proposed changes, we suggest that CMS clarify how any future proposed changes would be different from the current standards, whether new standards would be*

[28] https://www.ahip.org/health-care-leaders-collaborate-to-streamline-prior-authorization-and-improve-timely-access-to-treatment/

specific to electronic prior authorizations through the PAS API, and whether new standards would duplicate or replace existing standards.

Standardizing Question Sets

Also based on discussions during the listening sessions, CMS is seeking comments on potential solutions to standardizing prior authorization forms, including the possibility of developing an HL7 FHIR-based questionnaire for prior authorization requests.

One of the reasons cited by CAQH for lower adoption rates of electronic prior authorization for medical services versus pharmacy is that medical services may require more and varying types of clinical information and documentation than prescription drugs. This may make development of standardized question sets for medical services more challenging. At the same time, we recognize that consistency in certain aspects of the prior authorization process would reduce provider burden and increase efficiency. However, in an industry wide survey of health plans, when asked about the greatest opportunities to reduce variation in prior authorization programs, use of standardized prior authorization request forms ranked last.[29] The majority of respondents chose the use of electronic prior authorization technology (81 percent) and the process for submitting prior authorization requests (67 percent) as the greatest opportunities for reducing variation in prior authorization programs.

Recommendation:

- *CMS should collect additional information on the feasibility of developing standardized question sets, particularly for medical services, and provide sufficient time for the necessary APIs to be built and adopted by a critical mass of providers before proposing any changes.*

D. Payer-to-Payer Data Exchange on FHIR

1. Background

CMS previously finalized that plans in federal programs are required to share, at the member's request, a specified subset of clinical data with the member's next payer for up to five years after disenrollment starting January 1, 2022. For the subset of payers impacted by this rule, CMS is proposing several new policies related to this P2P data exchange:

- to require the exchange through a FHIR-enable API,
- to extend the requirements to state Medicaid and CHIP FFS programs that were excluded in the prior rule,
- to add claims and encounter data (not including cost information),
- to add active prior authorization decisions, and
- to offer the data exchange to members at enrollment.

[29] https://www.ahip.org/wp-content/uploads/Prior-Authorization-Survey-Results.pdf

CMS seeks to require health insurance providers to share health information in sequence as enrollees change plans to approximate a longitudinal health record that patients can access through third-party apps, providers can access it "at the bedside," and new payers can access the information from prior payers starting with data maintained back to January 1, 2016. We support appropriate sharing of enrollee information between health insurance providers as well as with patients and providers to promote effective care coordination. However, given the many proposals in this rule, we think CMS should reconsider which information is best to flow through which API and how the APIs will interact.

Given the many proposals in this rule, CMS should reconsider which information is best to flow through which API and how the APIs will interact. For the P2P exchange, we believe the focus should be on sharing information from one impacted payer to the next: the information that either assists impacted payers in streamlining the transition (e.g., minimizing the information required for a prior authorization) or the impacted payer is the source of truth (e.g., claims data). For other information, such as data originally derived from EHRs, we assert that CMS and ONC should focus the requirements on the providers' own API requirements to share data with each other, consumers (via third-party app) and payers as needed.

We also note that as members share data across payers, this will result in an enormous amount of data accumulating and being exchanged, especially in future years. CMS should consider ways in which it might be able to streamline where and how to get and store the information.

Recommendations:

- *CMS should provide at least an additional 45-day comment period on the Proposed Rule.*
- *CMS should not finalize the P2P API and P2P Exchange at Enrollment proposals effective January 1, 2023 but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*
- *CMS should consider which information is best shared by payers and find ways in which it might to streamline how the information is shared and stored by impacted payers.*

U.S. Core Data for Interoperability (USCDI)

The content previously required through the P2P API in the Interoperability Rule includes information health insurance providers have available that are in the USCDI standard (e.g., lab results). Impacted payers do not commonly collect information in the current USCDI, which is geared toward providers and EHRs. Some clinical information is furnished to health insurance providers (sometimes in electronic format) for administrative purposes, quality reporting, risk adjustment and utilization management. Much of this information would not be helpful for continuity of care when member changes issuers. For example, elements of quality measures at the individual level are often not clinically valid. For a blood pressure measure, a payer can choose one diastolic and one systolic value across three readings without the two "matching," rendering it clinically inaccurate and irrelevant. Other than clinical information collected as part

of a prior authorization, as we discuss below, we believe that little of the information in the USCDI that impacted payers maintain would be useful to the next payer or to providers and consumers.

ONC and CMS have already established open API requirements for providers and CEHRT. CMS should focus on providers sharing the most up-to-date, comprehensive, and relevant clinical information with consumers, other providers, and payers as needed through that mechanism. We believe that patients and providers alike would prioritize the clinical information from hospitals and clinicians over that of impacted payers. Providers are the originating source and have the most comprehensive clinical view of the patient, while impacted payers have fragmented secondary information collected for narrow purposes.

In addition, the clinical information shared by providers with payers are most often unstructured data with file formats such as PDF or JPEG because the 287i claims attachment standard has never been finalized. At this point in time, technologies such as natural language processing and artificial intelligence are not mature enough to parse large, non-standardized, static files for the data elements in the USCDI. Even if it were, the extracted data elements would then have to be warehoused in a database and converted to FHIR resources, which would be time and resource prohibitive at this stage.

Finally, it has also come to our attention that through informal guidance to stakeholders, CMS is taking the position that claims information is included in the USCDI. In the Interoperability Rule for the Patient Access API, CMS proposed and finalized the USCDI content and the claims content as two separate proposals. For the P2P exchange only the USCDI was proposed. If CMS had intended for payers to pull out the USCDI elements from the claims, as opposed to the files obtained from providers, it should have expressly proposed that and stated it in the final rule. While this point may be moot for impacted payers if CMS finalizes an exchange of claims and encounter data (not including costs) in this API, it would still be relevant for Medicare Advantage plans and to states until and if that provision were applied to them in a Final Rule.

Ultimately, the claims data and prior authorization decisions standardized in a FHIR-enabled format are what is in the possession of payers and valuable to consumers and providers, not the USCDI data elements obtained from providers outside of claims. If this information is paired with a requirement that providers share comprehensive clinical data (in a standardized FHIR-enabled format) with consumers and payers, then payers would be able to reduce unnecessary care, streamline prior authorizations, and auto-populate risk assessments, in a seamless, efficient, and effective way. We believe that by sharing claims information (without costs) and the clinical information associated with a prior authorization, there is no need for impacted payers to share USCDI within the P2P API. Moreover, as noted in prior sections, there appear to be overlaps in the various IGs including the USCDI Core and the PDex IG.

Recommendations:

- *CMS should remove the requirement that impacted payers share clinical information as represented by the USCDI v1 via the P2P API because providers are the source of truth*

for the EHR-based clinical data and CMS proposes to separately require impacted payers to share the clinical information contained in claims data.

- *CMS should also act to remove this requirement for payers subject to the Interoperability Rule but not this Proposed Rule. At minimum, CMS should act to align the timeframes and standards across both rules and all impacted payers to no sooner than January 1, 2024.*
- *CMS should, at minimum, clarify the overlap between the PDex IG and the CARIN Blue Button IG.*

2. Payer-to-Payer Data Exchange on FHIR

While CMS had previously finalized the P2P exchange, it did not dictate a particular technical standard at the time recognizing that payers customarily exchange information via X12 HIPAA transaction sets, but that some may want to use FHIR-enabled APIs. However, in this rule, CMS seeks to require a FHIR-enabled API. Additionally, while in the initial rule the expectation was that a single individual would be asking for data to be shared, in this rule CMS proposes that such information be shared at enrollment (as we discuss below) for many members at one time. Thus, CMS proposes to incorporate via cross reference that the API rely on the bulk data specs as proposed by ONC on behalf of HHS. CMS similarly proposes to require the use of the IGs referenced in the Patient Access and Provider Access APIs sections of this rule:

- 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;
- 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; and
- HL7 FHIR version 4.0.1 to facilitate the exchange.

AHIP and its members support CMS establishing FHIR as the exchange standard so that the payer community (at least those covered by this rule) can move forward with some level of uniformity. However, we have several questions and concerns about how this can be operationalized that we cover throughout this section. We recommend that these FHIR Implementation Guides be named as provisional standards, so that the industry and HL7 have an opportunity to further test and deploy them more widely, mature them as needed, and reach more clarity on the usability and interoperability of these guides. Having these as provisional instead of required would allow HL7 to receive industry feedback on any needed changes or improvements.

The bulk data specifications do not currently include aspects of the P2P proposal. Moreover, the IGs noted by CMS are geared toward payer to consumer or payer to provider exchanges, not payer-to-payer exchanges. We believe far more work is needed to ensure that the payer-to-payer exchange within the P2P API, and particularly, the P2P Exchange at Enrollment are adequately captured in the standards and IGs.

Finally, CMS suggests that it expects payers to *integrate* the other payers' data within its "maintained" records and be able to note the source once the data is shared with the next payer. Including this data into systems of record for decisions such continuation of or approval of a prior authorization would be challenging to automate. The key is to ensure the standards for the additional content – specifically, the pending or active prior authorization data – are clear and integrated into the appropriate IGs. This will also require impacted payers to create data tagging (provenance).

Recommendations:

- *We support CMS naming not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*
- *CMS should ensure that all named IGs are created and approved through an ANSI accredited Standards Development Organization with a fair and transparent process that includes public comment.*
- *However, we request clarification on the mapping of specific API functionalities to specific IGs as it is not always clear in the Proposed Rule, some functionalities do not appear to be captured in the IGs, and some elements overlap in the IGs (e.g., USCDI CORE IG or the HL7 Da Vinci PDex).*
- *CMS should not implement the P2P API or P2P Exchange at Enrollment effective January 1, 2023, but rather support the further development of prior authorization and other content and technical standards to support the API are developed and incorporated into the appropriate IGs for testing before inclusion in the regulations.*
- *Adopting or allowing the use of new versions of standards in regulations or guidance should follow their testing, implementation, evaluation, and refinement, and should occur only with clear and consistent public notice of schedule and public comment, as well as adequate time for implementation.*

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

CMS is proposing to extend the patient-initiated P2P Data Exchange requirements from the Interoperability Rule to state Medicaid and CHIP FFS programs. CMS chose not to apply the P2P exchange in the Interoperability Rule itself to states because it stated that it wanted the states to focus on implementing the Patient Access and Directory APIs.

CMS notes that it believes the new requirements leverage the same data and technical standards and nearly all the same IGs as the Patient Access API, and thus should not require significant resources to implement. We disagree with CMS and believe this will require new work for states at a time that they remain focused on addressing the current health crisis with significantly constrained resources. In the months since the finalization of the Interoperability Rule, the difficulties associated with implementing these technologies and polices have only grown more challenging while states have simultaneously had to focus their resources on responding to the COVID-19 pandemic. States will continue to play such a role as we progress along the

vaccination phases. Additionally, as noted above, the standards and IGs are not yet fully mature for these use cases.

If CMS extends this policy to the states, we agree with CMS that the requirement for the MCOs/CHIP plans should be extended to match the states. In several states, certain services (e.g., behavioral health) are carved out of managed care plans and instead are covered through FFS programs. The timelines and requirements should be aligned to better ensure a coordinated approach for affected beneficiaries.

Recommendation:

- *CMS should not finalize the P2P API and P2P Exchange at Enrollment proposals effective January 1, 2023 for states but rather reshape the provisions into a roadmap with staggered implementation dates that begin no sooner than January 1, 2024 and key off mature standards.*
- *CMS should ensure the content and technical standards have been defined, the IGs updated or newly developed, and additional pilot testing has occurred to alleviate.*
- *This effective date should be consistent for both states and other impact payers.*

4. Enhancing the Payer-to-Payer Data Exchange – Payer-to-Payer API

CMS is proposing that impacted payers must implement and maintain a P2P API to facilitate the exchange of patient information between impacted payers, both with the approval and at the direction of the patient and when a patient moves from one payer to another as permitted, and in accordance with applicable law. The API would support exchanging patient data including but not limited to: adjudicated claims and encounter data (not including cost information); clinical data as defined in the USCDI; and information related to pending and active prior authorization decisions.

Costs

We appreciate that CMS took into consideration AHIP's previous comments that it would not be appropriate to share cost information, in any form, across payers. We believe this would have a stifling effect on competition and is not relevant for the notion of creating a longitudinal health record. We believe there is value to consumers to be able to keep a long-term record of which services were furnished by which providers across time.

We note that the CARIN Alliance Blue Button IG only includes the FHIR standards component and does not map to the full X12 HIPAA-required claims transaction. Thus, it is a subset of the claim akin to an Explanation of Benefits (EOB) that would be shared minus the cost information.

The requirement in the regulatory text of the Proposed Rule specifies that claims and encounter information should be made available within or no later than "one (1) business day after receipt." The preamble language states that "We required that data must be made available no later than one (1) business day after a claim is adjudicated or encounter data are received". In the Interoperability Rule, the requirement is "one (1) business day after processing" or "one (1)

business day after adjudication." CMS should seek consistency across the rules for the same information. Moreover, it would be nearly impossible to share the information a day after receipt as processing must occur to ensure accurate information is shared.

Recommendation:

- *We agree with CMS that the information customarily included in an EOB could be valuable for consumers to share from one payer to the next and that the cost information should not be included in the exchange, but neither CMS in this Proposed Rule nor the IG currently delineates which specific elements would not be shared.*
- *CMS should edit the regulatory text to specify that the claims and encounter information be made available within "one (1) business day after adjudication" across all relevant APIs.*
- *CMS should ensure the content and technical standards have been defined, the IGs updated or newly developed, and additional pilot testing has occurred prior to inclusion in the regulation.*

Prior Authorization

CMS is proposing to require impacted payers to make available pending and active prior authorization (and related clinical documentation and forms) via the API and integrate this information into the patient's record to be available for review and consideration by other payers when a patient enrolls with a new payer. The proposed documentation would include the date the prior authorization was approved, the date the authorization ends, as well as the units and services approved and those used to date.

CMS is not proposing to require the new payer that would receive the prior authorization information and documentation under this proposal to specifically consult this information at this time. However, they are seeking comments for possible future rulemaking on the extent to which CMS should consider explicitly requiring payers to demonstrate that they have reviewed and considered these previous prior authorization decisions from a patient's previous payer before requiring patients to undergo a new prior authorization process. CMS is also considering whether to require payers to honor a previous payer's active prior authorization decisions at the time the enrollee moves from one payer to a new payer for some length of time.

We agree that the availability of information on prior authorization decisions from a previous payer could reduce burden and promote continuity of care and agree that the focus of this information should be on pending and active prior authorizations. Additionally, we support the exchange and sharing of this information using FHIR-enabled APIs. We note that prior authorization is not currently included in the HL7 Da Vinci Payer Data Exchange Implementation Guide and our same concerns regarding the interaction between the X12 278 and FHIR expressed under the PAS API comments would apply here as well.

If HHS chooses to finalize this proposal, CMS should revise several of the requirements to make implementation more feasible. First, CMS should clarify what precise information must be available on pending prior authorization decisions. Additionally, we have concerns about CMS

requiring the units and services used to date as part of the API because such data would need to be updated in real time as claims come in to be accurate and useful to those accessing the data through the API. Finally, CMS must ensure that the technical standards and related IGs reflect the relevant content and policies to allow for the seamless transfer of such information.

We have concerns with requiring a new payer to act in accordance with the decision of a previous payer for any extended length of time without review. This should be up to the new impacted payer, the circumstances of the case, and potential changes in the patient's comorbidities or health status. Not only do prior authorization policies differ by payer, but there are clinical reasons why regular review and reconsideration of prior authorization decisions may be warranted. For example, even when lab results are collected as part of a prior authorization request, there is no guarantee that those lab results have not changed in the interim and could impact the future course of treatment. Additionally, clinical guidelines are continually evolving, and recommended care could change during a patient's treatment.

Recommendation:

- *CMS should not finalize the effective date of January 1, 2023 for the prior authorization component of the P2P API or the P2P Exchange at Enrollment.*
- *We suggest CMS clarify how any of the additional prior authorization components of the Patient Access, Provider Access, PAS, and P2P APIs, would be different from each other as well as the current X12 standards, and whether the new standards would be duplicative or replace existing standards.*
- *We recommend that CMS work with the industry to define the specific data structure and data elements related to pending and active prior authorization before being included in the P2P API.*
- *CMS should withdraw the requirement that the pending and active authorizations include "the related clinical documentation and forms."*
- *CMS should require only the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date.*
- *Per our recommendations on the PAS API, CMS should consider existing standards on continuity of care in exploring any policy changes in this area. CMS should not require an impacted payer to abide by outdated prior authorizations by prior impacted payers.*

5. Payer-to-Payer API—Sharing Data at Enrollment

CMS is also proposing a second payer-to-payer data exchange policy that would use this P2P API to facilitate data sharing between payers at enrollment. When a patient enrolls with a new payer or when a patient identifies concurrent coverage, CMS is proposing that the patient would have an opportunity to opt-in to this data sharing. Unlike the payer-to-payer exchange finalized previously, where the patient must make a request to initiate the data sharing, under this proposal the patient would be presented with data sharing as an option at enrollment.

This new P2P API proposal to share data at enrollment would include a requirement for impacted payers to facilitate data sharing both for individual patients and for more than one patient using the bulk data specs. CMS would require impacted payers to share claims and encounter data (not including cost data), a sub-set of clinical data as defined in the USCDI version 1, and information about pending and active prior authorization decisions at enrollment, for payers that have a specific annual open enrollment period, or during the first calendar quarter of each year.

Current FHIR Resources are not based upon enrollment in a payer's plan. A system must be worked out for the new impacted payer to request the information from the previous payer (if it is also an impacted payer). This goes well beyond the existing standards and IGs. CMS has not indicated how the new payer will know who the prior payer was other than replies from the member that may not be complete or accurate enough to make the plan identification. Moreover, there is not a FHIR-enabled "Payer Directory" or centralized exchange mechanism leaving impacted payers to establish individual connections with each other payer from whom their members disenrolled resulting in a disjointed and inefficient system.

In addition, far more policy would need to be built out to successfully implement such an exchange beyond such technical issues. For example, if the request for transfer occurs at the time of open enrollment, this will miss the claims run out after disenrollment. CMS did not clearly specify if this is a one-time transfer. If there are claims (or prior authorizations or clinical data) after the transfer but before the member leaves the current payer, then the goal of having a complete health record that follows the member will have gaps in it.

CMS has not made it clear how impacted payers will be able to reconcile the requirements within this required API and state standards for the Medicaid, CHIP and QHP programs as well as the FFE. For example, it is not clear whether the states or MCOs would initiate this for Medicaid and CHIP enrollees or how this opt-in interacts with the broader data-sharing options offered to consumers when signing up for Medicaid/CHIP. For example, if the enrollee declines to opt-in to data sharing at the state level, would that supplant the MCO's process for offering the option to the enrollee separately? To complicate things further, some states have processes in place for consumers to opt-out rather than opt-in, and in some cases, this occurs through a state-wide health information exchange. If an enrollee declines to opt-out would they then be asked again to potentially opt-in to this process? This could leave out some enrollees who assume that they are going to be automatically enrolled. CMS should consider whether it could craft a policy that gives deference to the states own data sharing policies and processes.

In addition, the FFE facilitates enrollment in QHPs through the centralized healthcare.gov website. The same type of interaction questions apply here. Additionally, QHPs rely on the FFE to send standard HIPAA transactions (834) with any changes in enrollment. Additional elements and processes should be developed and maintained to facilitate the P2P API and P2P Exchange at Enrollment. For example, CMS could provide through the FFE the identifier of the prior issuer for purposes of transferring data between impacted payers.

Recommendations:

- *CMS should not finalize the effective date of January 1, 2023 for the P2P Exchange at Enrollment.*
- *AHIP recommends that CMS extend the timeframe for implementation of the P2P Exchange at Enrollment to at least January 1, 2024 or when the data standards have been defined, the IGs have been updated, and additional pilot testing has occurred before implementation.*
- *CMS should consider existing standards on continuity of care in exploring any policy changes in the P2P API per our recommendations on the PAS API.*
- *Before the proposed requirements can be adopted at scale, CMS in collaboration with ONC must seek industry adoption of the ONC FAST solutions for, at minimum, identity resolution, security, and directory.*
- *CMS should provide through the FFE additional information on the 834 to facilitate implementation of these requirements by QHP issuers.*
- *State enrollment and data-sharing processes should take precedence over the P2P Enrollment Exchange and CMS should clarify a set of parameters to govern the number and timing of data-sharing requests.*

Timelines

CMS is seeking comment on whether the timeframes for the new payer requesting these data – within one week of this enrollment or other defined period ending – and the old payer sending these data – within one business day of receiving the request – are the optimal timeframes and what other timeframes payers may want CMS to consider.

We concur with CMS that it is appropriate to overtly offer enrollees the option of bringing claims information (minus costs) and prior authorization decisions with them from a prior payer to a new payer. However, this policy should be staggered after CMS clarifies several policy and operational questions, per above, and impacted payers can create a process for enrollees to request data be shared.

Additionally, CMS should further consider how impacted payers will apply this policy to existing members. We are concerned that systems would be overwhelmed if they are required to transmit information on hundreds of thousands of former members within a single business day.

Recommendation:

- *If CMS proceeds with the policy to offer an opt-in to data sharing at enrollment, we recommend that plans be allowed to do a rolling offering for enrollees over a calendar quarter to minimize disruptions to systems and that the intersection between state and plan responsibilities be clearly defined prior to implementation.*

6. Extensions and Exemptions for Medicaid and CHIP

CMS is proposing a process through which states may seek an extension of and, in specific circumstances, an exemption from, the P2P API requirements if they are unable to implement these API requirements.

We support CMS's proposal to provide an extensions or exemptions process for the state FFS agencies. States are and will continue to experience severe economic repercussions because of COVID-19 including impacts on their economies, unemployment rates and fluctuating Medicaid enrollment. However, we note that all impacted payers, not just states, will have to go through a budgetary process, select vendors, and potentially hire staff.

Recommendations:

- *We agree with CMS that there is a need for extensions and exemptions for Medicaid and CHIP FFS programs for the P2P API.*
- *CMS should also clarify that a state can request a second extension, if circumstances warrant, in the following year rather than seeking an exemption from the start.*
- *CMS should proactively monitor for systemic impacts on states that would impact their ability to implement such policies, such as a termination of the enhance FMAP, and alter effective dates accordingly.*
- *We further urge CMS to create an exception and an exemption process across all APIs for all impacted payers.*

7. Exception for QHP Issuers

CMS proposes an exception that could apply to small issuers, issuers who are only in the individual or small group market, financially vulnerable issuers, or new entrants to the FFE who demonstrate that deploying standards based API technology consistent with the required interoperability standards would pose a significant barrier to the issuer's ability to provide coverage to consumers, and not certifying the issuer's QHP or QHPs would result in consumers having few or no plan options in certain areas.

We also support CMS's proposal to provide an exception process for the P2P API for QHPs like the one provided under the Patient Access API in the Interoperability Rule API. However, as noted above, we believe impacted payers of all types may have difficulty implementing these extensive requirements.

Recommendation:

- *We agree with CMS that there is a need for exceptions for certain QHP issuers to the PAS API.*
- *We urge CMS to establish both an exception and an exemption process across all APIs for all impacted payers.*

III. Requests for Information

CMS is seeking comment for potential future rulemaking on how to advance electronic data exchange among behavioral health providers, input on processes and uses of electronic prior authorization transactions exchanged between payers, providers, and patients, how CMS can reduce the use of fax machines across programs, and barriers to adopting standards related to social risk data.

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

CMS notes that stakeholders have expressed a desire for greater segmentation of patient data to be shared. CMS is seeking stakeholder feedback on the roles of patients and providers in data segmentation decisions, examples of effective tools and methods for patients and providers to control access to portions of patients' health data, information on the potential cost and burden of data segmentation at the data element level, current patient consent process, FHIR utility, technical considerations, and lessons learned from current segmentation efforts.

Response:

AHIP appreciates the need to ensure patients maintain control of their health data. However, currently data segmentation remains technically and procedurally difficult. Health insurance providers are not currently capable of implementing data segmentation; building such capacity would take significant resources. Implementing data segmentation will result in significant costs both from building the capability as well as from ensuring data segmentation preferences follow the data throughout the healthcare ecosystem. It can be challenging to know what data a health plan can and cannot share and to develop an automated system to share permissible data. We also continue to have concerns about patient privacy and processes must be adopted to ensure privacy is safeguarded throughout the segmentation process and when segmented data is shared.

Segmentation of condition data should be a consistent regulatory requirement instead of determined by the actions of each member. Using patient choice as a determination may conflict with what can be shared under state law. Moreover, providers and plans have long raised concerns with the current requirements of 42 CFR Part 2 regulations (Part 2) which negatively impact the ability of providers to coordinate care and present potential safety issues (e.g., drug interactions). Further data segmentation could exacerbate these concerns.

If CMS chooses to pursue patient choice as a determination for segmentation, that choice should be focused on external disclosures as it is much more difficult to control data availability within a health system (e.g., if providers within a system use a shared EHR system, it may not be possible to control access given the functionality of the EHR).

B. Electronic Exchange of Behavioral Health Information

CMS recognizes that behavioral health providers lag their peers in adoption of certified EHR technology and the ability to electronically exchange patient information. CMS is requesting information on how to leverage APIs (or other solutions) to facilitate electronic data exchange between and with behavioral health care providers, as well as with community-based organizations. CMS is specifically seeking comments on whether FHIR-based APIs could

facilitate data exchange without greater EHR adoption or if EHR adoption is required, what levers CMS could use to promote data exchange, considerations for certain types of behavioral health providers, and regulations that are perceived as barriers to data exchange.

Response:

AHIP appreciates CMS recognizing that behavioral health, small practices, and community organizations were included in the Meaningful Use incentive program (HITECH Act) and now lag in adoption of health information technology. A lack of EHR infrastructure is the main obstacle behavioral health providers face to exchanging electronic information. Investment through a program like the Meaningful Use program may help promote adoption. While building out capabilities to exchange FHIR-based APIs may not require complete certified EHR adoption, these groups still need to build out foundational elements such as data collection systems and protocols. This requires financial investments, time, and technical capabilities. Without necessary support and infrastructure, it should not be assumed that API adoption will be quick and painless for these groups. Additionally, provider education may be essential to convince behavioral health providers of the security of electronic data exchange and help providers shift their practice workflows. Finally, there may be a need for a consent process that permits bi-directional data sharing and comports with applicable state and federal law. We also note that this same disparity of adoption exists in providers who provide home and community-based services for individuals with long term health care needs. A comprehensive solution that thoughtfully examines and ensures all provider types are included is recommended rather than addressing different providers at different unaddressed points in time.

In addition, this could help facilitate the exchange social determinants of health data to better address members' needs. However, there may be challenges related to HIPAA and ensuring community organizations can receive such data from health plans and providers. Moreover, there is a lack of vetting processes for community-based organizations that could give health plans and providers confidence that sharing this data will be safe for the members. Finally, providers need additional support and guidance on how to collect this data and what type of data is the most impactful.

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

CMS is seeking comment for future rulemaking on how best to incentivize providers to use electronic prior authorization solutions. CMS is also seeking information on current barriers to transmitting prior authorization requests and receipts electronically, the efficiency and timeliness of current methods for electronic transmission of prior authorization requests and receipts, and the appropriateness of including an Improvement Activity under the MIPS to support the use of the PAS API.

Response:

Providers need evidence that the solution works, and they need incentives to use it. As previously mentioned, we recommend that CMS not finalize the effective date of January 1,

2023 for the DLRS and PAS APIs. Instead, we urge CMS to reconsider its proposed timeline and consider reshaping this rule into a roadmap with milestones along the journey that signal a new requirement is ready for implementation. Readiness for implementation should include CMS identifying and establishing assistance and incentives for providers to use the DLRS and PAS APIs in their workflows in parallel with the requirement on payers to create and maintain the DLRS and PAS APIs. We recognize that including an Improvement Activity under the MIPS to support the use of the PAS API would create such an incentive and promote adoption. However, CMS should consider if including such an activity could result in a disconnect between the incentive and the desired behavior. Moreover, the providers who may have the most difficulty adopting the APIs could be small and rural practices that are unable or unwilling to engage in MIPS or this type of aided prior authorization process, and other incentives would need to be developed for these providers.

Another way to reduce barriers on prior authorization is to advance value-based care that relies less on transactional medicine (aka FFS) and more on performance and outcomes. Moving to value-based care models would significantly reduce and even eliminate the need for prior authorization.

Finally, barriers could be reduced by establishing computable, electronically accessible health plan prior authorization policies and requirements available via APIs and decision support tools (e.g., HL7 FHIR-based CDS-Hooks) that integrate the documentation and other prior authorization support requirements with the EHRs before or during an encounter.

D. Reducing the Use of Fax Machines

CMS notes a desire to generally reduce or eliminate the use of facsimile (fax) technology across CMS programs, as possible and appropriate, as the use of fax technology limits the ability of the health care sector to reach true interoperability. CMS is requesting information on the current use of fax machines, the challenges payers and providers might face if use of the fax technology for health care data exchange is eliminated, how certain technologies could facilitate a transition away from fax machines, and if the elimination of the use of fax machines could impact disaster preparedness.

Response:

AHIP agrees with CMS that there is a need to reduce the use of fax machines for exchanging health information. Other modalities are more efficient and allow for more streamlined procedures and greater specificity. We would recommend CMS look to a suite of options to support the transition away from the use of fax machines. APIs are one solution but not all providers will have the infrastructure to support their use. Other solutions like electronic exchange via portal, direct secure messaging, and cloud-based fax technology may be more feasible short-term solutions for some providers.

Smaller providers and others who were left out of the Meaningful Use programs continue to lag in EHR adoption and may be more likely to depend on fax machines. Additional investment by

the government may be necessary to help these providers transition from the use of fax machines.

We also recommend that CMS consider the varying ability of providers to adopt to the APIs when considering the shortened turnaround times. While shortened turnaround times may be achievable with an API to which a provider connects, a longer turnaround time will be necessary for those providers that remain reliant upon their fax machines. For example, many federal, private, and state-supported data collection efforts are scattered and unsystematic, leading to barriers in aggregating and analyzing information in a manner that is useful for driving care delivery and interventions.

We also note that fax machines are often considered to be part of backup processes in the event of system unavailability. We suggest CMS consider relegating fax to an exclusively backup role. In addition, CMS could begin to reduce and ultimately eliminate requirements related to paper-based documentation.

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

CMS is seeking information on barriers to the adoption of industry-wide standards to collection social risk data, electronically represent these data, and enable exchange of person-centered data between medical providers and community-based organizations through health information technology platforms. Specifically, CMS is seeking information on the challenges in representing and exchanging social risk and social needs data from different commonly used screening tools, barriers to the exchange of social risk and social needs data across providers, what mechanisms are currently used to exchange social risk and social needs data, and how can health care payers promote exchange of social risk and social needs data.

Response:

AHIP appreciates CMS's recognition of the impact of social risk factors and the effect of these factors on value-based purchasing. One challenge in representing and exchanging social risk and social needs data from different screening tools is the lack of standardization across the tools as commonly used tools ask variants of similar questions making it difficult to aggregate the data. Moreover, there is a lack of common interoperable standards that support a bi-directional exchange of information. For example, many federal, private, and state-supported data collection efforts are scattered and unsystematic, leading to barriers in aggregating and analyzing information in a manner that is useful for driving care delivery and interventions.

There are numerous barriers to exchanging social risk and social needs data across providers as well as exchanging such data between providers and community-based organizations. The most significant challenge may be the limited amount of data available. The causes of this paucity of data are manifold. First, it can be burdensome and expensive to collect social risk data while current practices can lead to unintended consequences and bias. There is also no single proxy to identify specific social determinants of health (SDOH) or outcomes. Another key challenge is the fragmented communication/coordination between sectors providing clinical, social, and human

services, and with individuals and communities served. This fragmentation limits the effectiveness of resource availability and allocation, impacting quality of care and health outcomes, and can be a source of frustration or confusion for individuals needing services. Other key barriers include verifying individuals uniquely, proprietary technical infrastructure, lack of technical infrastructure (access to human services administrative data is generally not stored or shared outside of government agencies and there is no existing modern technical infrastructure to support it), lack of common lexicon and standardization across data, and lack of real-time eligibility and enrollment information for state-administered social and human service programs.

Additionally, there may be challenges related to HIPAA and ensuring community organizations can receive such data from health plans and providers. While we appreciate the some of the flexibilities proposed in the Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (HIPAA Proposed Rule) whereby certain entities can share information with social service organizations, we are concerned about the lack of vetting processes for community-based organizations that could give health plans and providers confidence that sharing this data will be safe for the members. Finally, providers need additional support and guidance on how to collect this data and what type of data is the most impactful.

We agree with the need for greater adoption of standards related to social risk. Greater standardization could help address these challenges. AHIP supports the Gravity Project's work to standardize SDOH data. We are also supportive of increased use of ICD-10 Z Codes. ONC could help accelerate this work by incorporating social risk data into USCDI. Additionally, CMS could adopt a MIPS practice improvement activity around increased use of the Z Codes as well as aligning payment models with social health outcomes measured through standard code sets and terminology.

There may also be a need for the development of a consensus set of technical standards for social risk data and best practices for collecting it that could be shared and used across sectors (healthcare, housing, transportation, etc.). CMS should support the development of HL7 FHIR implementation specification that are used to capture, document, use, exchange social risk information.

One way to incentivize use of social risk data is to allow it to be built into rates and included in the numerator of the medical loss ratio calculation, as opposed to categorized as an administrative cost. This would help reflect the true value of social risk data services and ensure patients are receiving the care they need.

Finally, CMS should support industry efforts to develop new metrics that help measure the outcomes of social health as it integrates with clinical care and public health (e.g., the National Alliance for the Social Determinants of Health and through other channels).

IV. Incorporation by Reference

While the ONC CEHRT Program does not apply to payer APIs under this and the prior rule, we have concerns that ONC is not proposing any changes. As we note earlier, providers and EHR

vendors must be held to comparable standards for the Provider Access API, DRLS API, and PAS API to connect seamlessly with the impacted payers. CMS and ONC should ensure that comparable standards are adopted by providers and vendors at the same time as they are required for impacted payers.

Moreover, we are not clear that CMS can publish a proposed rule that includes policies under the purview of another agency without that agency also proposing the policies. This appears to have led to CMS naming certain IGs that do not cover the proposed exchanges. Standards and related IGs must be complete, tested, and stable before implementation of these provisions to avoid members having to "rip and replace' systems.

Finally, given the truncated comment period we were not able to thoroughly review and prepare comments on the standards themselves and the related implementation guides.

Recommendations:

- *ONC should ensure that the proposed standards and IGs fully cover the proposed policies and have been tested for such use before inclusion in regulation*.

VI. Response to Comments

CMS notes that because of the large number of public comments it normally receives on *Federal Register* documents, that they are not able to acknowledge or respond to them individually. However, it will consider all comments it receives by the date and time specified in the DATES section of this preamble, and, when it proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administration is obligated to review and summarize all comments and take them into consideration in its final policies. Should the Administration attempt to finalize this rule before January 20th, we assert that the government could not consider adequately stakeholder comments on this economically significant rule in just over two weeks.

Recommendation:

- *We urge CMS not to finalize this regulation until comments can be reviewed, synthesized, considered for changes, and responded to in the final regulation.*

VII. Regulatory Impact Analysis

The Proposed Rule estimates in Table 19 that the 10-year total costs for implementing this rule could be as high as $2.8B. Even with the potential $1.1B in economies that it believes could be achieved by using electronic prior authorization shown in Table 16, CMS estimates the rule would still cost as much as $1.79B.

We have serious concerns that CMS has significantly underestimated likely costs, particularly as the estimate fails to account for inefficiencies and potential duplicative work that will occur because of the inadequate implementation timelines in the Proposed Rule. For example, as noted

elsewhere, development, testing and implementation would be required at the same time plans are working to comply with the first Interoperability Rule. Further, IGs are likely to change over this period. Such an unstable environment will inevitably lead to delays, unnecessary costs, and other operational challenges. These impacts reinforce the need for CMS to provide additional time for comment so that stakeholders can perform a more complete analysis of likely costs and the agency can appropriately assess potential costs and benefits of the Proposed Rule. The impacts also support the requirement for longer implementation timelines.

Not only do we believe CMS has underestimated the costs, but we also believe it has overestimated the efficiencies associated with the PAS API. Impacted payer and provider burden will increase when attempting to align FHIR and 278 transactions independently. New back office capabilities will need to be developed to align independent data transactions on the send and receive steps prior to inserting the desired data into an internal workflow. To alleviate this inefficiency, as we note above, HHS should remove the ceiling approach 278 and enable the FHIR-based transactions to allow for the freedom to achieve the desired efficiency and outcomes. And, CMS and ONC should apply comparable to providers and CERHT vendors. Otherwise, CMS's estimates of achieved economies will be significantly overstated.

In addition, even if CMS estimates were accurate, Table 19 in the preamble indicates that roughly one third of total costs will occur in 2021 and 2022 alone, the same time states and other stakeholders need to devote increasing resources toward addressing the pandemic while struggling to respond to its severe economic impacts. We are concerned about the magnitude of the costs associated with this rule and urge CMS to pare back the requirements and reintroduce some provisions later. We agree with CMS that a significant portion of the costs would be incurred up-front, when development, testing, etc. will take place, while benefits will be realized further into the future. Accordingly, the Proposed Rule would impose new burdens on impacted payers, Medicaid and CHIP programs, and in turn state budgets, during the same period they may still be struggling with the pandemic and its after-effects.

Recommendations:

- *CMS should not finalize the effective date of January 1, 2023 for the rule.*
- *We urge CMS to reconsider its proposed timeline and consider reshaping this rule into a roadmap with milestones along the journey that signal a new requirement is ready for implementation.*
- *CMS and ONC on behalf of HHS should ensure further comments are sought before any policies are finalized.*
- *In the meantime, CMS should update its impact analyses based on changes in the FHIR standards and the associated IGs that would be needed to implement these proposed changes.*

Sincerely,

Matthew Eyles
President & Chief Executive Officer