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March 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services

Submitted electronically: http://www.regulations.gov

RE: Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P)—AHIP Comments

Dear Administrator Brooks-LaSure:

Patients deserve high-quality care delivered by doctors and health insurance providers working together and sharing reliable health information. Guided by this commitment, AHIP's[1] health insurance provider members work tirelessly to offer coverage for high-quality care that helps maintain wellness and improve health outcomes. Data and technology are key to these offerings to ensure that Americans and their doctors have the information they need to make informed health care decisions. To that end, AHIP is committed to developing policy solutions that will ensure meaningful access to actionable information for patients, promote quality and affordability, and keep personal health information private and secure.

We appreciate CMS's efforts to improve data access and interoperability, and we recognize the important role of payers in these efforts. AHIP and its members wholeheartedly support the underlying goal of moving toward a health care system in which data flow seamlessly among appropriate stakeholders to the benefit of Americans. We also support the specific objectives of achieving interoperable exchange through application programming interfaces (API) between payers and patients, payers and providers, and payers with other payers. Furthermore, we support implementing technologies that will permit physicians to look up payer coverage and documentation requirements as well as conduct electronic prior authorization requests and responses. Given that, we appreciate that CMS recognized the need to place requirements on providers to use the prior authorization technologies, but CMS should add additional incentives,

[1] AHIP is the national association whose members provide coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

such as publicly reporting use of ePA, to strengthen those policies. Our concerns with the proposed rule, and thus our recommended changes, generally center on how and when to implement these complex and resource intensive health information technology initiatives.

We urge the Administration to consider the timing of these policies in the context of the broader scope of requirements and challenges facing the industry that require significant systems changes. To provide some examples, those health insurance providers that support both plans in federal programs and commercial plans have shown great leadership in implementing the Transparency in Coverage[2] machine-readable files and web-based cost calculator tools on time and are busy refining their operations. These same health insurance providers are planning for the implementation of the advanced explanations of benefits called for in the No Surprises Act (NSA). Health insurance providers with Medicaid and commercial lines of business are also gearing up for the massive effort that will be required to conduct Medicaid redeterminations and shift enrollees to the Marketplaces. Moreover, the whole industry will be making necessary systems changes to unwind the COVID-19 public health emergency and implement the commercialization of those items that were heretofore paid for by the government.

The most direct interference with implementation of this rule is the Administrative Simplification Notice of Proposed Rulemaking (CMS-0053-P)[3], also published by the agency, that would require the update of several Health Insurance Portability and Accountability Act (HIPAA) electronic transaction standards, as well as the implementation of a new claim attachment standard including for prior authorization purposes. While this rule requires Fast Healthcare Interoperability Resources (FHIR®) standards for prior authorization, the Administrative Simplification proposed rule would require an X12-based transactions for the same purpose. Given the decades-long wait for the X12-based claim attachment standard, the industry took the initiative to develop FHIR-based standards for both the claim attachment and the prior authorization transactions. It would be the antithesis of administrative simplification if the agency moves forward with two different standards for the overlapping case of prior authorization at the same time.

In addition, there are several foundational standards and infrastructure components missing to successfully implement these policies now. The technical standards and implementation guides (IG) necessary to support implementation of the APIs are not yet sufficiently mature. While we support the use of FHIR-based APIs, the standards and IGs must be fully defined and tested at scale to ensure the data can be feasibly and consistently shared across stakeholders. The current level of maturity depends on the use case, which would lend itself to a phased in approach as

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[2] https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage
[3] https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

they progress. Furthermore, there is significant work to be done to ensure the technical infrastructure is ready to support these exchanges. For example, if payers must electronically share data with one another and providers, a national directory containing each organization's digital endpoint is key. Otherwise, amassing all the necessary endpoints is a highly manual process. We were encouraged by CMS's recent request for information on the creation of a National Directory of Healthcare Providers and Services (NDH). A public-private partnership would not only assist with improving the accuracy of directories broadly but also could support both the Provider Access and Payer-to-Payer APIs.

We further believe there may be a potential missed opportunity if the Technical Exchange Framework and Common Agreement (TEFCA) infrastructure is not harnessed and aligned with these requirements. This could ease the development of an endpoint directory, facilitate consumer identification and consent, streamline third-party app registration, enable efficient large-scale file exchange, and provide a method to accumulate personal health records more comprehensively from all their payers and providers while better protecting the privacy of the information exchanged. Concurrent efforts to resolve these infrastructure interdependencies will be highly critical to the success of these policies.

For these reasons, we urge CMS to consider this rule within the broader landscape of health information technology regulations and create consumer-centric, streamlined requirements that deliver effective, efficient, and secure ways to provide data to patients, reduce clinician burden, and facilitate the movement of data between payers and care settings in a manner that neither diminishes privacy nor increases costs. While our detailed comments are attached, our high-level recommendations are:

- Develop a roadmap, in partnership with the private sector, for all the technical use cases across the Interoperability rule, NSA transparency provisions, and the Administrative Simplification rule.
- Invest in the necessary infrastructure to support interoperability, including the NDH and payer use cases as part of TEFCA.
- Ensure the implementation timeline takes a cohesive, stagged approach to strengthen consumer trust, reduce burden and duplication for stakeholders, and improve the end product.
- Remove prior authorization from the Administrative Simplification rule and finalize a FHIR-based transaction.
- Prioritize the prior authorization provisions, then focus on a narrowed scope for the Payer-to-Payer API, and finally implement the Provider Access API.
- Ensure no policies are enforced until the standards and IGs have been finalized, tested, and scaled.

- Support testing of FHIR end-to-end, without conversion to X12, for the full electronic prior authorization process among willing trading partners to develop lessons learned and demonstrate the return on investment.
- Ensure adoption of the APIs required in this rule by placing commensurate requirements on providers to use the APIs and EHR to build the necessary connections.

Our comments and recommendations reflect AHIP's commitment to develop policy solutions that will reduce provider burden, ensure Americans have access to their data, and promote high-quality, safe, and efficient care. 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, consumers, and health care providers. If you have any questions, please reach out to me at either dlloyd@ahip.org or 202-778-3246.

Sincerely,

Danielle A. Lloyd
Senior Vice President, Private Market Innovations & Quality Initatives

II. A. PATIENT ACCESS API

II. A. 2. a. Prior Authorization Information

CMS proposes to add information about prior authorizations to the categories of information that must be made available via the Patient Access application programming interface (API) as finalized in the Interoperability and Patient Access final rule (Interoperability Rule)[1] applicable to states and plans in federal programs (impacted payers).[2] This proposal would apply to all prior authorization requests and decisions for items and services (excluding all drugs) for which the payer has data, regardless of the technology used to receive the request and whether the decision is still pending, active, denied, expired, or is in another status.

AHIP supports the goal of empowering patients with access to their health information. An ability for patients to track the status of their prior authorizations would increase transparency and permit better engagement in their care plan. However, the requirements to share prior authorization information with consumers through APIs are not yet feasible to implement as proposed. Moreover, as detailed in our comments on the Patient Access API metrics, use of the Patient Access API remains limited. CMS should allow for implementation of certain components of the Prior Authorization Requirements, Documentation and Decision (PARDD) API before requiring prior authorization information to be shared via the Patient Access API. **CMS should revise the proposal and its implementation date to ensure successful implementation per our comments below.**

Recommendations:

- *Do not require the addition of prior authorization information to the Patient Access API until after the industry has implemented the PARDD API for electronic prior authorization but permit voluntary early adoption sooner.*

Required Data Sources

AHIP agrees that moving toward industry-wide adoption of electronic prior authorization (ePA) transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. However, adoption of ePA is still lagging. Health insurance providers strive to ensure access to needed items, services, drugs, and care are available for all patients. As such, health insurance providers have implemented multiple methods to ensure prior authorization requests and processes work for all providers. Currently, prior authorizations requests can be made by phone, fax, web-based portal, or via an electronic health record (EHR). However, allowing prior authorizations to be submitted via multiple methods limits the ability to easily make information received from methods like phone or fax available electronically. **If CMS finalizes the requirement to add prior authorization information to the Patient Access API, it should clarify that the requirement only applies to requests received via ePA requests (whether through the PARDD API or an X12 278—Health Care Services Request**

[1] 85 FR 25558– 25559

[2] Medicare Advantage organizations (MAO), state Medicaid and CHIP fee-for service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges (FFEs)

for Review and Response (006020X315) transaction. However, CMS should also clarify that payers could make additional information available if they so choose.

Recommendations:

- *Limit the requirement to make prior authorization available via the Patient Access API to only data contained in standardized ePA exchanges.*
- *Clarify that payers would be able to send a broader set of prior authorization data at their discretion.*

Required Data Elements

CMS proposes that payers would be required to make certain information about prior authorizations available via the Patient Access API within two business day from the provider submitting an ePA request. Furthermore, the documentation required to be shared includes any materials that the provider sends to the payer to support a decision, for example, structured or unstructured clinical data including laboratory results, scores or assessments, past medications or procedures, progress notes, or diagnostic reports.

Quantity Used to Date

CMS should revise the required data elements to remove the quantity of services used to date under the authorization. Payers depend on finalized claims to capture whether a service has been consumed. This data is dependent upon the provider submitting the claim and the payer processing it, which will almost always lag the course of treatment. The 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 expended within one business day. Given these limitations, the information on the quantity of services used to date that would be available via the Patient Access API will almost always be wrong and therefore misleading to the member and to the provider.

Related Clinical Documentation and Forms

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 Fast Healthcare Interoperability Resources (FHIR©) resources. In fact, CMS has taken the position via a Frequently Asked Question[3] 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. Moreover, the unstructured documentation may include especially sensitive information like patient photographs that could be particularly concerning to patients if released with their other clinical and encounter information.

In addition, the structured information in the supporting documentation would be redundant to clinical data already available to patients from providers via the Patient Access API. The

[3] https://www.cms.gov/about-cms/obrhi/faqs#111

supporting documentation uses clinical data already available in the person's record to allow the payer's medical personnel to review the submission and would not provide new or unique information to the patient. **CMS should not finalize the proposal to require payers to provide the supporting documentation over the Patient Access API.**

Recommendations:

- *Withdraw the requirement that the pending and active authorizations include "the related clinical documentation and forms."*
- *Require only the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date.*

Timeframe for Populating the API

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 feasible if the information is not received electronically in a standardized format. It would be a significant burden on payers to transfer information received via phone or fax to interoperable formats in that short of a timeframe.

A more feasible option would be to require availability within two business days of receipt of the request via a standardized electronic transaction (whether X12 278 or corollary FHIR-based transaction). CMS should extend the timeframe from one day to two business days to accommodate the conversion of information into interoperable elements for all forms of ePA, including an API. CMS should not require non-electronic data (e.g., requests made by fax or phone) to be included in the Patient Access API.

As a related matter, CMS should name a baseline version of the X12 278 transaction to request an authorization from a payer consistent with whichever version is named in the Administrative Simplification proposed rule[4] currently under review. Although, CMS should also permit a fully FHIR-based exchange should that be permitted by the Department of Health and Human Services (HHS) through a waiver of the X12 278 (and X12 275 should that be finalized). To the extent that transactions can be consolidated to not only the same standards but the same versions the efficiencies will grow and the timeframes will shorten.

We also note that for delegated requests, a payer will often only receive notice of a request and then an update on the final disposition, and as such should not be required to include interim status changes. Per the prior rule, payers should not have to obtain access to information it would not otherwise have to meet the requirement.

Recommendations:

- *Revise the proposal to require prior authorization information to be made available within two business days of receipt of a request via a standardized electronic transaction.*

[4] https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

Information on Prior Authorizations for Drugs

CMS also seeks comment on whether it should consider policies to require impacted payers to include information about prior authorizations for drugs (when the payer covers drugs) via the Patient Access API and how such requirements might interact with existing prior authorization requirements and standards.

We support the agency's proposal to limit the prior authorization policies in this regulation to items and services other than drugs. AHIP agrees with having future discussions on the potential value of including information about prescription drugs and/or covered outpatient drugs 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, in some cases two different entities, 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 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.

Additionally, we recommend CMS work with stakeholders and standards development organizations to adequately develop and test voluntary standards for inclusion of drug information. Longer-term discussions, as well as metrics to show the success of the currently proposed provisions for ePA, are necessary.

We request that CMS clarify that nothing in this regulation would prohibit payers from voluntarily sharing data on prior authorization requests for drugs. Depending on a payer's IT system it may be more difficult to filter requests for drugs versus items and services while other payers rather than provide all the information. This appears to be allowed by the regulatory text, but we would appreciate clarity.

Recommendation:

- *Develop the policy further before including prior authorization information for drugs in the Patient Access API.*
- *Clarify that nothing prohibits payers from voluntarily sharing data on prior authorization requests for drugs.*

Timeframe for Information Retention

CMS proposes to require that information about prior authorizations (and related administrative and clinical documentation) be available via the Patient Access API for as long as the authorization is active and at least 1 year after the last status change. CMS notes the agency does

not propose to require that payers share a patient's full prior authorization history because that could comprise a significant amount of information that may no longer be clinically relevant and would be redundant to clinical information contained elsewhere in a patient's record.

We support the proposal to only require information about prior authorizations be available via the Patient Access API for as long as the authorization is active and at least 1 year after the last status change. We agree with the agency that older authorizations would not be clinically relevant, and that the information would be redundant to clinical information elsewhere in the record. However, we ask CMS to clarify that payers could remove inactive, older authorizations in batches at set intervals (e.g., remove them quarterly or annually, rather than exactly one year after the last status change).

Recommendations:

- *Finalize the proposal to only require information about prior authorizations be available via the Patient Access API for as long as the authorization is active and at least 1 year after the last status change.*

Technical Standards

AHIP supports naming not only the base standards but also the specific implementation guides (IGs) associated with ePA. We further recommend that a specific version of the IGs be named as a floor and that a formal standards version advancement process (SVAP) be developed and adopted in regulation, similar to the ONC SVAP process under their Health IT certification program.[5] For example, CMS could propose FHIR 5.0 as the base standard, and name the floor version 2.0 of the associated FHIR IG. When version 3.0 of the IG is available, that could advance through the SVAP without needing rulemaking. However, when version 6.0 of the base standard is released, CMS would then go through the regulatory process to adopt both the version 6.0 of base standard and associated 1.0 version of the IG as the new floor. Through this process the technology would be allowed to evolve, but major new base standards would still be subject to public comment. This will give the industry and HL7 the opportunity to continue refining, testing, and deploying new versions of the IGs, yet ensuring the industry implements these policies in a consistent manner.

We are concerned that without a requirement to use specific IGs we will not achieve the level of industry-wide interoperability necessary to support this data exchange. However, given the development and maintenance of standards and IGs are an extension of federal policy that does not go through the rulemaking process, it is critical that this development and maintenance process be consensus-based, fair, transparent, and open to all stakeholders. And, that policy decisions are not delegated to this process, but rather through formal agency mechanisms. For example, the IG creation process is currently driven by a limited number of volunteers that do not broadly represent the industry, which results in creates IG Resource/Profile versioning issues. Ensuring there is no fee to fully participate in the process for the regulatorily required exchanges and relying on an ANSI accredited process to develop the IGs would improve the approach.

We are concerned about the lack of maturity of the current IGs that have not been broadly tested for the purpose of sharing prior authorization information. There are currently no well-defined

[5] https://www.healthit.gov/topic/standards-version-advancement-process-svap

data standards or transaction sets for prior authorization information. Prior authorization status using FHIR-based standards is defined in the HL7 Prior Authorization Support (PAS FHIR IG). At the same time, HL7 is balloting an updated version of the HL7 Da Vinci Payer Data Exchange Implementation Guide (PDex). However, additional specifications and wider industry testing is needed to strengthen and mature these IGs.

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 mandating the inclusion of prior authorization in the Patient Access API. We strongly recommend that these elements be fully defined in the PAS FHIR IG first and fully tested in the context of the PARDD API, before updates are made to PDex and tested for inclusion in the Provider Access API. The initial focus should be on launching ePA with providers via the PARDD API as the precursor to being able to share status with consumers via the Patient Access API.

Recommendations:

- *Name not only the base standards but also the specific IG versions as a floor and create a SVAP.*
- *Ensure IGs are created and approved as part of a consensus-based, fair, open and transparent process that is ANSI accredited and does not require a fee to comment or participate.*
- *Adopt new versions consistent with a SVAP process to be defined in regulations, and only after sufficient time for testing, implementation, evaluation, refinement, and public input.*
- *Delay the addition of the prior authorization information to the Patient Access API until the PARDD API is developed, implemented, and tested so that lessons learned can be integrated into the Patient Access API implementation.*

II. A. 2. B. Interaction with HIPAA Right of Access Provisions

CMS notes that an individual patient generally has a right of access to inspect and/or obtain a copy of protected health information (PHI) about themselves in a designated record set for as long as the PHI is maintained in the designated record set by a covered entity.

AHIP supports the ability of consumers to access their PHI. We believe the proposals are intended to provide greater access to PHI beyond the traditional methods (i.e., submitting a request to an entity and waiting for a paper copy of records to be mailed) and to bring the consumer experience into modern, electronic processes. CMS and the HHS Office for Civil Rights (OCR) should explain in guidance or future regulations how the existing HIPAA requirements that allow individual consumers to access their PHI apply to covered entities and consumers using the new CMS' API processes.

II. A. 2. C. Privacy Policy

CMS requests comments on how it can help give patients the tools they need to understand the privacy and security implications of using an app within the scope of the agency's regulatory authority.

AHIP recognizes the potential of APIs to give patients access to their health data, a valuable tool to help them engage in their health and health care. However, with these new opportunities come new threats to patient privacy. New entity types, such as app developers, that are now common

in the marketplace were not contemplated, let alone included, as covered entities within the traditional Health Insurance Portability and Accountability Act (HIPAA), Health Information Technology for Economic and Clinical Health **(**HITECH**)**, and 42 CFR Part 2 rules.

These new entities can be collecting, using, disclosing, and disseminating consumer health data for the purpose of monetizing it, and yet consumers are generally unaware that the data are outside these regulatory protection frameworks. AHIP continues to be very concerned about the potential for bad actors to exploit data gained via the APIs and the potential consequences for patients and their families. This risk grows exponentially as additional data elements are required to be shared with third-party apps not governed by the health care privacy legal requirements. For example, sensitive patient data, at an individually identifiable level, shared by a payer with an app developer under these new CMS required policies can be freely sold or disclosed as long as it is noted in the consumer terms and agreement provided by the app (which can be changed at any time). In April 2019, a JAMA© report found that 36 of the leading depression and smoking cessation apps in the U.S. and Australia routinely share user data with third parties, but just 12 third-party app developers accurately disclosed the practice within the privacy policy.[6][7] In addition, research[8,9,10] shows that third-party apps pose an unprecedented risk to consumers' privacy given their ability to collect user data that is highly valuable to commercial interests as well as their ability to re-identify consumers in other de-identified datasets. Moreover, consumers are also often unaware that the more individually identifiable data released, the easier it becomes for de-identified data to be reidentified.[11]

The privacy and security of member data is a paramount responsibility and a major concern for health insurance providers and the consumers they serve. Thus, we appreciate CMS seeking ways in which to address potential privacy concerns that could arise because of its regulations requiring payers to share information with third-party apps. We also thank the agency for recognizing that requiring privacy attestations from third-party app developers, as proposed in the December 2020 rule, would have created undue collecting burden, and suggested tacit approval of third-party apps by payers without providing meaningful protections.

Below, we provide CMS with recommended policies and actions to protect patient privacy while ensuring consumers can easily access their health data.

Data Elements

As noted above, the risk to a person's privacy and cybersecurity grows exponentially as more data is shared. ONC continues to add new data elements to the United States Core Data for Interoperability (USCDI) continues to expand, several of which provide personally identifying information that would not provide value to consumers. For example, in USCDI version 3, the

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[6] https://www.consumerreports.org/health-privacy/mental-health-apps-and-user-privacy-a7415198244/, https://www.statnews.com/2022/12/13/telehealth-facebook-google-tracking-health-data/

[7] https://www.scmagazine.com/analysis/application-security/senators-target-security-privacy-risks-of-mental-healthapps-misuse-of-health-data

[8]https://subscriber.politicopro.com/article/2023/02/data-broker-marketplace-research-shows-loose-controls-on-sensitive-mental-health-info-00082407

[9] https://www.washingtonpost.com/business/2019/04/22/smoking-depression-apps-are-selling-your-data-google-facebook-study-finds/

[10]https://www.wsj.com/articles/popular-apps-cease-sharing-data-with-facebook-11551044791

[11] https://techpolicy.sanford.duke.edu/data-brokers-and-the-sale-of-americans-mental-health-data/

health insurance information data class includes information about a person's relationship to the subscriber and group identifier. These data elements would provide data about a person's spouse or parent and where they are employed. Consumers already know this information, but third-party apps could use it to identify someone in a different data set or even re-identify a de-identified data set. The use case for USCDI is somewhat different; it is geared toward what should be available in a standardized manner in an EHR where the data is safely protected by HIPAA. Rather than adopting versions of the USCDI wholesale, CMS and ONC should consider the contribution of each data element and whether it is necessary to share through the Patient Access API and expose to the risk of passing to a third-party app that is not covered by HIPAA.

Recommendation:

- Only require sharing of personally identifiable information that consumers do not already have through the Patient Access API.

Member Education

All stakeholders, including payers, should play a role in patient education regarding data sharing. For example, in many cases payers have created alert systems to notify consumers when they are about to authorize making their data available to third-party apps. However, we believe HHS, leveraging public programs (e.g., Medicare, Medicaid, CHIP, etc.), in collaboration with other government entities, should take the lead in educating consumers on their rights, the risks, and benefits to accessing data via third-party apps.

As noted above, CMS and OCR should develop materials for consumers to provide information about their rights under HIPAA and the interaction with these innovative technologies and modern processes. HHS, collaborating with the Federal Trade Commission (FTC), should take the lead in making consumers aware of the risks and implications of granting data sharing access to third-party apps not regulated by HIPAA and how to lodge complaints specific to those apps. Given CMS' experience 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. This will also provide consumers with a streamlined government resource they can reference throughout their healthcare journeys. CMS could also use its authority to share the information it obtains from its vetting process for Medicare data to establish ratings of third-party apps on its website.

We recognize that the agency developed some resources[12] based on the rules, but we believe easy-to-understand documents with a consumer focus would help explain complex regulations in practical, common situations. These materials could be used across payers and providers for consumer education and would avoid the appearance of implied endorsement of an app. It should be made clear to consumers that HIPAA protections do not apply and that the health care or health insurance provider furnishing the data on their behalf are not responsible for the privacy or security of the data obtained by third-party apps, sold by the third-party apps, or when such data are used for secondary uses. These materials should also alert and inform patients on the limitations and risks related to allowing access to Substance Use Disorder (SUD) records and

[12] https://www.cms.gov/files/document/patient-privacy-and-security-resources.pdf and https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index

disclosures that are subject to the federal 42 CFR Part 2 rules, as well as information about other sensitive conditions (e.g., HIV status, mental health conditions), and state laws and regulations that can impact privacy and security because they have specific rules for certain types of health data (e.g., what services minors can access without parental consent).

CMS gained expertise through the launch of Blue Button and there is a strong consumer need for information about third-party apps. CMS should use the expertise the agency gained through the Blue Button launch to set up a voluntary program by which third-party apps could demonstrate--in a manner to be determined by CMS--their compliance with essential consumer protections. CMS should then publicize the third-party apps that have done this on its website and use the website as part of its education campaign (e.g., "before you install this app, give it a check up on HHS-App-Doctor.com.")

- *Collaborate with other federal agencies and stakeholders to develop and disseminate standardized education materials for consumers about the privacy and security risks of using third-party apps.*

Privacy and Security Regulatory Framework

While we support efforts to improve individuals' access to their PHI through the existing Patient Access APIs, we believe a national privacy framework to ensure that health care data obtained by non-HIPAA regulated third-party apps and services is held to high privacy and security standards should be a critical requirement for APIs. AHIP supports expanding legal requirements to entities that collect, use, disclose, or store individuals' health and health-related information (including social needs). To coordinate with transparency and interoperability efforts, privacy requirements should be designed and applied across all entities capturing, maintaining, or disclosing health and health-related information to allow the exchange of health information without reducing privacy protections. We recommend that FTC's authority and scope of oversight be expanded to offer a privacy and security structure that mirrors HIPAA to include entities that currently are not subject to privacy and security requirements. Such a process should be parallel to HIPAA but should not create additional requirements for entities already covered by the HIPAA and HITECH Act framework.

Recommendations:

- *Work with Congress to extend the FTC's authority and scope of oversight to apply robust consumer privacy and security protections similar to HIPAA.*

National App Certification

We appreciate CMS encouraging app developers to follow current best practices such as the CARIN Alliance's Code of Conduct and the ONC Model Privacy Notice (MPN) as a "stop gap" measure. However, such attestations are not sufficient to protect patients as adoption is not only voluntary, but there also is no legal recourse by patients or payers should an entity violate the terms of the attestation. While this may be one option, CMS should not preclude or exclude other private sector initiatives that may be more robust.

The CARIN Code of Conduct Accreditation Program (CCCAP)[13] conducted by the Electronic Healthcare Network Accreditation Commission (ENHAC) is an emerging private-sector solution that seeks to validate the entity is following the attestation, which is one step further. However, given impacted payers cannot currently deny requests from third-party apps that are not accredited, the accreditation is more of a marketing tool to boost consumer confidence. Moreover, if accredited entities fail to meet their obligations, the payers still have no legal recourse on behalf of themselves or consumers. The only penalty for the entity would be losing accreditation as it is not tied to any sort of regulatory framework. Plus, payers do not know which third-party apps have applied but failed such an accreditation process, so it only captures the positive aspects when we really need to know the negative ones.

Given that the Interoperability final rule did not allow payers to deny a request, CMS should work with ONC, OCR and the FTC to establish a regulatory framework and process to vet and potentially certify third-party apps in line with the CCCAP for the privacy and security of the information contained and the adequacy of their consumer disclosures. Such a certification process could either be done directly by the FTC or the FTC could work with stakeholders to establish a private sector process that has the support of the government. A second alternative is that since CMS gained expertise through Blue Button and there is a strong consumer need for information about third-party apps, CMS could use the expertise gained to set up a voluntary program by which apps could demonstrate their compliance with essential consumer protections. CMS should then publicize the third-party apps that have done this on its website and use the website as part of its education campaign. By establishing a new system that provides for app oversight, the FTC and/or CMS could ensure third-party app developers understand the expectations of their products and ensure patients receive consistent information and understanding on which apps may be the best choice for their needs.

CMS should also work with other federal agencies to ensure that third-party apps that are known to put at risk the information systems of health insurance providers, or that are violating the terms of their consumer privacy information, are listed in a centralized reporting site, so that providers and health insurers can be aware of them and take appropriate precautions.

Recommendations:

- *Work with the FTC, ONC, and OCR to establish a National App Certification Program, whereby third-party apps are vetted and certified for the adequacy of the consumer disclosures, as well as the privacy and security of the information.*
- *Work with these other federal agencies to create a site to list third-party apps that are bad actors.*

Payer Review of Adherence to Attestations

CMS seeks comments on ways to leverage the MPN to give consumers the information they need about the potential privacy and security implications of using an app. CMS asks if payers should notify patients the first time the patients request data through an app, whether the third-party app utilizes the MPN or not or if payers be required to list apps that have established access to their API on their websites that comply with the MPN's transparency requirements.

[13] https://www.ehnac.org/carin-code-of-conduct-accreditation-program/

We strongly discourage CMS from implementing polices that require payers to give an appearance of responsibility for or endorsement of third-party apps, since payers are unable to deny access to an app of a patient's choice and vetting third-party apps would be extremely burdensome, redundant (if each payer has to do it), and unreliable (as vetting is a point-in-time situation). Such policies may also lead consumers to assume an implied endorsement of specific apps.

Requirements for payers to track an app's utilization of the MPN would create an undue burden and put payers in the position of confirming whether a third-party app is actually using the MPN, which could be interpreted as a payer giving assurance of an app's compliance with using and administering the provisions in the MPN. Moreover, making each third-party app developers complete such a process for each payer individually could jeopardize access for members of smaller payers. We appreciate CMS addressing our previous public comments and rejecting a process that would require payers to collect an attestation from app developers. We urge CMS to continue rejecting policies that put the burden of vetting third-party apps on payers. We also urge CMS to consider our recommendations regarding establishing a national third-party app certification program mentioned previously. We believe requiring each health insurance provider to maintain its own vetting system and to engage in such processes would be overly burdensome and could mislead consumers about what entity is ultimately responsible for legal compliance.

CMS should not require payers to serve as intermediaries between third-party apps and patients. Health insurance providers do not have any ability to control which third-party app a patient chooses to use. For example, the proposed rule asks if payers should notify patients, the first time the patients request data through a third-party app, whether the app utilizes the MPN or not. The preamble also requests feedback about whether payers should publish lists of apps that have established access to their APIs that follow the MPN.

It is an unreasonable expectation for CMS to require payers to step in between a member and a third-party app as the policy is structured. As noted above, payers have no ability to control which apps seek accreditation such as the CCCAP or fail to meet their obligations under accreditation or attestation. Payers have no contractual or legal relationship with third-party apps they do not develop or offer to their members and as such cannot rectify an app's non-adherence to privacy policies. Given that a payer generally cannot deny a request from a member to send their health information to a third-party app, a payer is in the position of fulfilling an individual's request to use an app without having any legal authority to ensure such app's privacy and security protections.

Recommendations:

- *Develop a national consumer education campaign in collaboration with other federal agencies.*
- *Do not adopt policies that would require but permit impacted payers to collect attestations from third-party apps and publish information on the app developer's adherence to privacy policies***.**
- *Avoid policies that require payers to collect attestations and make it clear in the final rule that impacted payers do not have oversight or ongoing management requirements over third-party apps.*

- *Establish a National App Certification Program in collaboration with other federal agencies.*
- *Should CMS pursue future policies requiring impacted payers to confirm adherence by third-party apps to privacy practices, then no liability should attach to impacted payers that follow the rules in good faith and cause them to rely on information provided by app developers.*
- *Provide further guidance for consumers, payers and others on navigating the complex problem of state privacy and other implicated laws.*

Leveraging TEFCA and Other HHS Information Exchange Initiatives

CMS seeks comments on how the agency could leverage and build on other health information exchange initiatives, such as the Trusted Exchange Framework and Common Agreement (TEFCA), to address privacy and security issues. CMS also seeks comment on whether CMS should explore requirements or ways to encourage exchange under TEFCA to ensure that more patients are informed about the privacy and security implications of using third-party apps to access their health information, consistent with the requirements for Individual Access Services (IAS) providers.

AHIP supports the TEFCA processes which are building the policies and technical infrastructure on HIPAA's privacy and security framework. We also support CMS using this regulation to define opportunities that leverage and promote TEFCA participation.

The health care industry is moving toward increased interoperability of records and improved electronic transactions for routine administrative processes such as prior authorization and related functions. TEFCA should create a national network for health care information exchange among both HIPAA-covered and non-HIPAA covered entities. At this stage, TEFCA participation is voluntary, and more work has yet to take place for the health industry to understand what entities will be approved to act as Qualified Health Information Networks (QHINs). We support TEFCA's six expanded exchange purposes, including treatment, individual access service, public health, benefit determination, payment (utilization review), and health care operations (quality assessment and improvement, business planning and development). We also support CMS encouraging exchanges using TEFCA to ensure that more patients are informed about the privacy and security implications of using third-party apps to access their health information, particularly for the IAS function. This support may garner more engagement and participation with TEFCA.

The TEFCA processes are building in governance and operating requirements parallel to the HIPAA privacy and security requirements for all participants in that ecosystem, even if they are not HIPAA covered entities, with the goal of ensuring robust protections no matter what role the entity plays. A single weak link in the chain could compromise the entire ecosystem. By using such processes, legal privacy and security requirements are set in the governance structures, contracts, technical specifications, and standard operating procedures. These parameters set the legal expectations for privacy and security within TEFCA and steps that can be used if privacy or security is violated.

Health insurance providers and other stakeholders need to see value from TEFCA to devote time and resources. However, at the moment, TEFCA's exchange purposes seems very limited for the

type of exchanges health insurance providers perform every day. Having CMS requirements as part of TEFCA could bring greater value to health insurance providers and others. At present, we see this area as lacking and encourage CMS to do more to spur the TEFCA processes through a combined federal "push" for increased interoperability.

Recommendations:

- *Encourage TEFCA enforcements of privacy and security parameters in electronic exchanges.*
- *Encourage expansion of TEFCA exchange purposes to include other every-day exchanges performed by health insurance providers, such as prior authorizations, exchange of clinical documentation, and others.*
- *Work with ONC to design a specific pilot project that uses a specific population (e.g., Medicare beneficiaries in a specific geographical area) that use TEFCA and who could provide their perspectives from a consumer view on what works and what could be improved (i.e., a voluntary consumer focus group).*

Availability of Accessible Third-Party Apps

Additionally, CMS requests comments on the availability of third-party apps that are accessible to individuals with disabilities, availability of third-party apps in a multitude of languages to ensure that individuals with limited English proficiency can understand the information provided, and availability of third-party apps at an appropriate literacy level and in plain language.

We encourage CMS to work with the FTC to define parameters of accessibility for third-party apps used in health care and monitor the availability of such accessible apps. As currently implemented, payers have no control over which third-party apps offer which services, the design of these apps, whether they meet accessibility parameters, or whether patients use them. Moreover, there are no clear-cut criteria established to evaluate an app for accessibility, inappropriately placing the burden for creating a system on the impacted payers. If CMS adopts our suggestion noted above to work with the FTC to develop a National App Certification Program for vetting third-party apps, information on accessibility could be collected as part of that process. CMS should not require impacted payers to vet third-party apps and assess whether the apps are accessible by a variety of groups/populations. Additionally, similar to the HIPAA and non-HIPAA provisions previously discussed, certain third-party apps may not have experience with or are not required to adhere to Section 508 compliance or other accessibility provisions that CMS-regulated entities must follow.

II. A. 2. d. Patient Access API Metrics

CMS proposes to require impacted payers to report metrics in the form of aggregated, de-identified data to CMS on an annual basis about patient use of the Patient Access API. Specifically, CMS proposes that impacted payers annually report the:

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

We support the collection of question number one on an annual basis to assess the uptake of the APIs to influence future policymaking, but not question two. Health insurance providers are not responsible for promoting the use of specific technologies, such as third-party apps. AHIP is concerned that question two suggests payers are responsible for whether consumers see continued value in the third-party apps with which they share information. A metric assessing data transfer to a third-party app more than once reflects the quality and user experience of the app, not whether the impacted payer has met its obligations. Moreover, this metric 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. Additionally, this metric could be influenced by default settings of an app. An app can be configured to seek updates at certain intervals but that does not mean the member has requested the data. Finally, CMS must clarify question two given that the configuration of a typical FHIR dialogue permits a request to be counted in different ways and results could become skewed.

CMS proposes to require MAO to report these data to CMS at the organization level, state Medicaid and CHIP FFS programs to report at the state level, Medicaid managed care plans to report at the state level, CHIP managed care entities to report at the state level, and QHP issuers on the FFEs to report at the issuer level. CMS seeks 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. **If CMS chooses to finalize this proposal, it should not require reporting at the contract level.** AHIP members report a very low number of requests to date and further breakdown of the metrics could lead to small sample sizes and skewed data. CMS should also provide guidance on how to report integrated duals products.

Recommendations:

- *Implement only question one on an annual basis and remove question two.*
- *Collect the information at the organization or state level, not the contract level.*
- *Clarify what is meant by "the number of unique patients whose data are transferred more than once" if CMS proceeds with question two. Given the configuration of a typical FHIR dialogue, a request could be counted in different ways and results could become skewed.*

<u>Request for Comment on Public Reporting of the Patient Access API Metrics</u>

CMS notes the agency does not plan to publicly report these metrics at this time but may reference or publish aggregated and de-identified data that does not include names of specific state agencies, plans, or issuers. CMS solicits comments on this aspect of the proposal.

We agree with CMS that these measures should not be publicly reported at this time. As noted above, we do not believe they would provide accurate information about a payer's efforts to educate members, promote the use of third-party apps, or about the quality of its API, and AHIP members have found low uptake of the Patient Access API to date. If CMS implements these metrics, they should only be used for evaluation of the effectiveness of the agency's policies. Any sharing or publication of the results of the metrics should be aggregated and de-identified rather than attributed to an individual payer.

Request for Comment on Other Patient Access API Metrics

CMS also seeks comments on additional metrics that could be implemented in the future, whether payers could use existing demographic data to identify disparities in patient access, and the benefits and burdens of requiring payers to report the names all third-party apps that patients have used to access the payers' API each year.

We do not believe that additional Patient Access API metrics should be considered at this time and CMS should not require payers to publish the results of any metrics assessing use of the Patient Access API. While such metrics may have use in evaluating the effectiveness of CMS's policies, they do not reflect a payer's efforts to educate members or implement the Patient Access API. Use of the API will be driven by factors like a patient's intrinsic motivation and the user experience of the app. Further, we note that it would be practically impossible to be able to differentiate between the developer and the actual name of the application.

We urge CMS not to require reporting of the Patient Access API metrics by demographic factors. Health insurance providers are committed to advancing both health equity broadly as well as digital health equity specifically and are mindful of the need to avoid a digital divide as we advance interoperability and embrace health information technology. However, payers currently have incomplete demographic data, minimizing the likelihood data would be available on a specific member making a request of the Patient Access API without adding the additional burden of questions to collect demographic data before granting access. It would also be challenging to understand if a request is coming from the member themselves or an authorized representative who may not share their same demographics (e.g., spouses who are of different races or ethnicities). An authorized representative could also not be a member, making it very unlikely the payer would have demographic data.

Moreover, AHIP members have reported a low number of attempts to access the Patient Access API. Breaking down the access attempts by demographic factors would place an undue burden on payers to rework systems to track this information and could jeopardize patient privacy. Gathering demographic data for reporting use would be particularly difficult, as tokens expire after three months, and metrics would not know whether the person-access is the same or a new member accessing the API. Additionally, the collection of these metrics may not account for patient preferences for portals or other information resources aside from third-party apps. As noted above, we have concerns about the security of patient data after it's transferred to third-party apps and the risks of re-identifying consumers. Publicly reporting data broken down by demographic characteristics could give bad actors additional data points to re-identify a consumer and expose their health information. If CMS, does proceed with requiring the publication of certain applications used by patients, it should be reported on the most often used applications.

II. B. PROVIDER ACCESS API

II. B. 2. Proposed Requirements for Payers: Provider Access API for Individual Patient Information

CMS proposes to require payers to establish a Provider Access API and that patient claims and encounter data (excluding cost information), data elements identified in the USCDI version 1,

and prior authorization requests and decisions be available to in-network providers through this API beginning January 1, 2026. This proposal defines an in-network provider as any provider or health care facility that is part of a specific health plan's network of providers with which it has a contract.[14]

AHIP agrees that appropriate sharing of enrollee information between and among health care and health insurance providers can promote effective care coordination. Streamlined data sharing could 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 and the capacity of provider with whom the data is shared. 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.

While AHIP and its members see the value in a Provider Access API, we believe that it needs to be a bidirectional exchange of information between impacted payers and providers to reach its true potential. We see three major use cases: 1) facilitate the access and sharing of retrospective claims data from payers to providers to support population health and quality measurement; 2) support access and exchange of retrospective clinical information from providers to payers for quality measurement, utilization review, risk adjustment, and fraud detection; 3) enable access and exchange of dynamic data to support patient care, such as identified care gaps to providers and admit/discharge/transfer (ADT) alerts to payers. These use cases could also be supported by TEFCA. We note that the prior interoperability regulations did not include payers in the required provider ADT data exchange, but plans have seen great value in access to this data to enable alerts to providers and reduce unnecessary readmissions. CMS should set the stage for this aspirational vision in the final rule, but also recognize that sharing of real-time data to support patient care is not yet operationally feasible. The patient care use case would require up-to-date data that can be easily parsed on both the payer and provider sides to support clinician decision-making at the point of care.

CMS should initially focus the Provider Access API on the transfer of static files to providers, as proposed, but in parallel work with ONC to ensure the bidirectional flow of data based on the 21st Century Cures Act (Information Blocking) regulation provisions. Furthermore, CMS should consider the potential role of advances like TEFCA to support scaled exchange of large data sets on a more real-time basis in the future. CMS should also work with ONC to certify new standards for EHR vendors to ensure providers can participate in a bidirectional exchange.

We support CMS's proposal to limit data sharing to in-network providers. These guardrails allow payers to share data with providers who have an established and ongoing treatment relationship with a patient and who a payer has had an opportunity to vet. For example, requiring payers to share data with out-of-network providers could risk inadvertently sending data to providers who may be on the Preclusion or Exclusion lists, such as the Office of the Inspector General's (OIG) List of Excluded Individuals/Entities (LEIE) or the General Services Administration (GSA) Exclusion List. To prevent misuse of the Provider Access API by potential bad actors, CMS

[14] In the case of Medicaid and CHIP FFS programs, it would be any providers or health care facilities that are enrolled with the state as Medicaid or CHIP providers.

should not require out-of-network data sharing until this process has matured and been tested to ensure there are appropriate methods to protect patient data. CMS should also clarify that leased networks should be treated as out-of-network for the purpose of the Provider Access API as impacted payers not directly contract with these providers.

We ask CMS to clarify the definition of a "treatment relationship." Would this apply to only the rendering provider, or would CMS expect a billing provider to also have access to the Provider Access API? Similarly, CMS should clarify the expectations for in-patient / institutional Provider Access API functionality. Would an institution be able to submit a request as a provider of items and services? If so, is the billing provider also deemed to have a treatment relationship with the member? Would all providers involved in an in-patient stay be included in the data sharing? What is the best way to attribute the member to a provider for treatment purposes under these circumstances?

Recommendations:

- *Rename the exchange from Provider Access API to Payer-Provider Access API.*
- *Work with ONC to create companion requirements for providers to share clinical data with payers, under the Information Blocking provisions.*
- *Explore how advances like TEFCA could support these use cases as well as more real-time, targeted exchange.*
- *Finalize the proposal to limit data sharing requirements to in-network providers.*
- *Clarify and narrow the definition of a treatment relationship and the expectations for sharing data with institutional providers and/or billing providers.*

<u>Streamline Data Elements to Share</u>

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.

However, as noted in our response to the Patient Access API provisions of this rule, CMS should streamline the required data elements to avoid the sharing of duplicative information. CMS should not finalize the proposal to require sharing of the supporting documentation for a prior authorization request as this information will be redundant to the clinical information in a person's medical record and can be obtained by a provider from the treating provider through the provider APIs under the Information Blocking rule. We also reiterate our concerns about sharing data on the number of items or services consumed under an authorization as this information must be generated from finalized claims and will almost always lag treatment. This could be further delayed if there are claims adjustments for any reason, which would further make this requirement unduly burdensome. CMS should also clarify that the interoperability regulations do not require payers to share denied claims through the Provider Access API, the Patient Access API, or the Payer-to-Payer (P2P) API.

Recommendations:

- *Withdraw the requirement that the pending and active authorizations include "the related clinical documentation and forms."*
- *Require only the approved number of units (such as approved visits) for a specific prior authorization and not the units and services used to date.*

Protect Patient Privacy in the Information Exchanges

CMS notes in the rule that the provider would request and receive access to the patient's information through their EHR, practice management system, or other technology solution for treatment purposes, including care coordination. A health care provider would be using the information for treatment, but also permitted administrative functions (e.g., quality measurement). The proposals in this section appear to consider providers in a limited treatment context and overlook the innovations in care made through integrated delivery systems, accountable care organizations, and other alternative care delivery systems. In addition, other health care entities will need to use the information for treatment, payment, and health care operations (TPO). If these policies are finalized as proposed, payers will likely be connecting with a vendor, and not a health care provider directly, and these data flows need to be planned and anticipated. We recommend that the policy and regulations need to be revised to better align with HIPAA's uses and disclosures for TPO.

We recognize that the Provider Access API should fit into a provider's workflow to maximize adoption; however, these policies as proposed raise concerns about the need to ensure data is used for its intended purpose and that the requests are technologically feasible. There is a risk, as constructed, that EHRs and other vendors may set up a default request for records to retrieve data on all patients each day whether needed by the physicians or not. Such requests for such large files that must be re-cut based on newly updated attribution results could overwhelm payer systems. There is also the potential for this to violate the Minimum Necessary provisions under HIPAA depending on the purpose of its use. ONC should develop criteria in the CEHRT program to prevent such automatic pulls of data.

This exchange purpose should not be used as a means for EHRs and other vendors to obtain large de-identified data sets to monetize. There is a difference between sharing information between covered entities for TPO on behalf of enrollees and creating data sets to support other organizations' business opportunities. Moreover, the Administration should take care not to create market dynamics that displace the rich information and analysis already provided freely by impacted payers and substitute it with costly vendor analyses. We should be working to not only create the interoperability infrastructure necessary to share large claims files, but also to share dashboard analytics so that payers can continue to share digestible data with providers who do not have the capability to ingest large-scale files without vendor assistance.

The Provider API should be confined to the data necessary for TPO purposes. Thus, if CMS were to require an opt-in, which would be unnecessary under HIPAA, it should clarify that such authorization does not render the data outside of HIPAA as is the case under the Patient Access API. It should be clear that vendors shall not be permitted to combine the data with other data, other than that specific provider's data, or derivatives of data used for commercial purposes. Impacted payers should not be required to share data with outside vendors to create algorithms,

benchmarks, and similar products that leverage consumer data, for sale to others. The HIPAA Privacy Rule has restrictions for sale of PHI and non-HIPAA entities should be required to follow the same restrictions. Not only does that create a level-playing field for health care entities but it would ensure consistent privacy and security protections apply.

CMS should clarify that automated vendors requests of patient records and that a provider must proactively request the records through the vendor system. Moreover, CMS should work with ONC to ensure that the CEHRT program requires that records requests can only be initiated by a provider, given EHRs are the most likely connection point to receive these files, and must be based on a treatment relationship with a member, and must be requested for specific TPO functions, with minimum necessary provisions applying, as applicable. Providers should also be required to attest that the data should be used for such TPO functions, like health care delivery, population health management, or quality improvement. CMS should also work with ONC to clarify the responsibility of the EHR vendor to only pass data to the provider and that vendors may not use or keep data beyond the minimum necessary to support the provider request.

CMS should also consider adopting policies for the Provider Access API that mirror the policies for concurrent payers to exchange data via the Payer-to-Payer (P2P) API, outlined below, on a quarterly basis. We suggest CMS explore similar timeframes around the Provider Access API. CMS should only require impacted payers to respond to a request from a provider for a certain patient's data once a quarter. Such guidelines could ensure that vendors do not set a default for daily retrievals of data that risk sharing more information than necessary or overwhelming a payer's system with unnecessary and redundant requests.

Recommendations:

- *Work with ONC to ensure that the standards in the CEHRT program prevent auto-requests for records and that the requesting provider has a treatment relationship with a enrollee.*
- *Do not implement an opt-out or opt-in by enrollees given this should be confined to uses permitted under TPO.*
- *Consider requiring impacted payers to respond to a request from a provider for a certain patient's data only once per quarter to avoid auto-requests and to avoid sharing data with providers who no longer meet attribution requirements as they are generally run quarterly.*

Technical Standards

AHIP supports naming not only the base standards but also the IGs. We further recommend that a specific version of the IGs be named as a floor and that a formal standards version advancement process (SVAP) be developed and adopted in regulation, similar to the ONC SVAP process under their Health IT certification program.[15] For example, CMS could propose FHIR 5.0 as the base standard, and name the floor version 2.0 of the associated FHIR IG. When version 3.0 of the IG is available, that could advance through the SVAP without needing rulemaking. However, when version 6.0 of the base standard is released, CMS would then go through the regulatory process to adopt both the version 6.0 of base standard and associated 1.0 version of the IG as the new floor. Through this process the technology would be allowed to

[15] https://www.healthit.gov/topic/standards-version-advancement-process-svap

evolve, but major new base standards would still be subject to public comment. This will give the industry and HL7 the opportunity to continue refining, testing, and deploying new versions of the IGs, yet ensuring the industry implements these policies in a consistent manner.

Having said that, as we note above in the Patient Access API section, we have concerns about both the process and the maturity of the IGs. In particular, we have concerns about the operational challenges associated with implementing the prior authorization information in the Provider Access API. 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 mandating the inclusion of prior authorization in the Provider Access API. We suggest that these elements be fully defined in the PAS FHIR IG first and fully tested in the context of the PARDD before updates are made to PDex and tested for inclusion in the Provider Access API. The initial focus should be on launching ePA with providers via the PARDD API as the precursor to being able to share status with consumers via the Provider Access API.

Recommendations:

- *Name not only the base standards but also the specific IG versions as a floor and create a SVAP.*
- *Ensure IGs are created and approved as part of a fair and transparent process that is ANSI accredited and does not require a fee to comment or participate.*
- *Adopt new versions consistent with a SVAP process to be defined in regulations, and only after sufficient time for testing, implementation, evaluation, refinement, and public input.*
- *Prioritize the Provider Access API after the PARDD API and initially focus on data sharing of retrospective claims data before introducing other functionality so that the operational details and standards can be developed, implemented, and tested.*
- *Delay the prior authorization information component of the Provider Access API until the PARDD API is developed, implemented, and tested so that lessons learned can be integrated into the Provider Access API implementation.*

Build the Necessary Infrastructure

CMS should advance the HL7® FHIR at Scale Taskforce (FAST) initiatives to address the ongoing challenges of patient matching and identity management, digital identity, security and authentication, and access to the necessary digital endpoints. The ONC Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (Information Blocking Rule)[16], as well as the Interoperability and Patient Access Final Rule and this proposed rule, all establish policies focusing on the connection between each payer, each member/patient, and each individual app developer and/or each individual provider. The FAST initiative, which includes 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 FAST foundational and infrastructure solutions is required:

Directory—An application program interface (API) directory that can be referenced to know a provider's or payer's API endpoint address. FAST recommends funding and development of this

[16] RIN 0955-AA01, 84 Fed. Reg. 7424 [March 4, 2019]

directory. We also recommend CMS and ONC fund and complete this work before the APIs in the proposed rule are regulated.

We are encouraged by CMS's recent request for information on the creation of a National Directory of Healthcare Providers and Services (NDH). **The NDH will be essential to the success of the Provider Access API as information on provider's digital endpoints remains limited.** As noted in CMS's Request for Information many providers still fail to share data on their digital endpoints through the National Plan and Provider Enumeration System (NPPES), despite CMS's efforts to add these fields to the database and require their completion.[17] Without a comprehensive NDH and requirements for providers to complete the necessary information, implementing the Provider Access API will be challenging.

Security—A security framework 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.

In addition, the HL7 Da Vinci payer-to-payer IG depends on Mutual Transport Layer Security (MTLS) to establish the identity of each of the organizations involved in the exchange. Other payer to provider or payer to member exchanges rely on OAuth and the SMART framework. The Health Record Exchange (HRex) Coverage Profile allows for Unified Data Access Profiles (UDAP) as a viable solution that is in production and may replace MTLS if proven sufficient. Moreover, HL7's FHIR at Scale Taskforce (FAST) published STU1 of the security IG[18]; which should be considered foundational in the future for all IGs that require registration, authentication, and authorization. To future proof authentication procedures, CMS should support industry discussions and actions toward UDAP alignment across IGs, when and where appropriate.

We also note that for legal reasons, some payers may wish to continue seeking wet signatures from organizations. Some plans do this for every FTP/SFTP or other connections. CMS should clarify that requiring wet signatures continues to be appropriate when the impacted payer deems it necessary.

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 matured and tested prior to the APIs becoming mandatory.

Recommendations:

- *Work with ONC to encourage adoption of the HL7 FAST solutions for, at minimum, identity resolution, security, and directory so that the requirements can be adopted at scale.*

[17] https://www.federalregister.gov/documents/2022/10/07/2022-21904/request-for-information-national-directory-of-healthcare-providers-and-services
[18] HL7.FHIR.US.UDAP-SECURITY\Home - FHIR v4.0.1

- *Encourage HL7 to integrate UDAP into its IGs.*
- *Name not only the specific standards, but also the IGs as provisional standards as a floor to achieve further consistency across the industry.*
- *Clarify 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).*

Ensure Use of the Provider Access API

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. Health insurance providers are concerned with having to build another API and then seeing poor adoption of this newer technology capability by providers and their EHR systems. 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 Provider Access 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 a one-sided requirement of impacted payers.

Recommendations:

- *Include incentives for providers within the Promoting Interoperability category within the MIPS program and Promoting Interoperability program for hospitals to use the Provider Access API in their workflows in parallel with the requirement on payers to create and maintain the API.*
- *Work with 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.*
- *Monitor the status of Provider Access API implementation and adoption of CEHRT standards to determine the appropriate time to adopt financial incentives for providers to use the Provider Access API.*

Promote Data Sharing Across the System

CMS and ONC's proposals to date are one sided— requiring plans to build new API capabilities and to share information with providers, but not requiring providers to reciprocate as the Information Blocking final rule and Interoperability final rule did not include provisions requiring information sharing with payers. For example, as part of these rules, providers must

make admission-discharge-transfer (ADT) alerts available to other providers. However, they are not required to share such information with payers. Knowing these key steps in a patient's inpatient care journey would enable health insurance providers to better assist in care coordination, follow-up, and improving patient outcomes. This is a known point where errors and communication breakdowns occur, and health insurance providers are uniquely positioned to intervene in these situations and ensure enrollees receive coordinated care across settings and over time. Real-time alerts available to health insurance providers would allow timely interventions that claims data do not support. CMS should work with ONC and HL7 to build the necessary infrastructure changes including developing a standard for ADT data and ensuring payer digital endpoints are known by provider systems and vice-versa. CMS should also work with ONC to propose processes (either through bidirectional APIs or TEFCA) to share this data with payers.

Ensuring such data flows in a private and secure manner among all appropriate stakeholders, including from providers to payers, stands to greatly improve the efficiency and efficacy of care and operations as well as further engage consumers. CMS and ONC should implement parallel data sharing requirements on providers and EHR vendors to allow payers to become more active partners in care coordination and to promote safe transitions. CMS could explore ways to make the Provider Access API bidirectional or place requirements in the CEHRT program for EHR vendors to build a similar API to allow payers to access their members' clinical data.

Request for Comment on Sharing Data with Out-of-Network Providers

CMS seeks comments on potentially requiring sharing data with out-of-network providers in the future and encourages payers to share information via API with out-of-network or unenrolled providers who have a verified treatment relationship with the patient, to the extent permitted by law.

As noted above, data sharing through the Provider Access API should be limited to in-network providers. We have concerns about the ability to properly vet out-of-network providers before sharing patient data with them and risking possible privacy and disclosure violations. 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 validate the provider's eligibility to access the data. And, if a physician is not enrolled with the plan, how to distinguish between an app developer and a physician making a request. 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 health care, and what happens if the patient choses to cancel the appointment, but the data has already been shared. Moreover, patients can access their data through the Patient Access API to an app of their choosing to share information with their providers.

II. B. 3. A. Attribution

CMS proposes to require that payers develop an attribution process to associate patients with their providers to help ensure that a payer only sends a patient's data to providers who are requesting that data and who have a treatment relationship with that patient that the payer can identify. CMS notes that the Argonaut Project has developed an implementation guide specifying how to use FHIR's Scheduling and Appointment resources to communicate this information. We are reviewing the Argonaut approach, which is largely driven by providers, and are concerned that developing a technical approach before a policy approach is putting the cart before the horse and inappropriately delegating policy decisions to a standards organization.

We note that CAQH CORE has also developed attribution operating rules[19] to be integrated into the X12 270/271 that we have significant concerns with from a policy perspective, as articulated in a recent comment letter to National Committee on Vital and Health Statistics (NCVHS)[20]. Not only do we believe an appropriate attribution process must first be worked out in rulemaking, but we are concerned that we will yet again be faced with overlapping and potentially conflicting standards.

Attribution is a notoriously challenging aspect of the transition to value-based care and health care measurement. Often, a patient's identification of 'their doctor' may not match the results generated through automated approaches. An analysis of claims is a proxy metric for a patient provider relationship not determinative. Moreover, most attribution processes currently are geared toward identifying a singular accountable primary care physician (although in some cases it may be a group or a specialist) within value-based arrangements. We appreciate CMS recognizing the lack of an industry standard and not proposing an overly prescriptive approached. We agree with the agency that approaches to attribution are evolving and that payers would be able to use different processes to attribute patients to providers as long as we can exchange the results. However, it is not clear if CMS intends the attribution process to identify a single clinician, a practice, or even multiple physicians (e.g., specialists). Attribution approaches in this instance must be able to support one-to-many relationships (one patient with multiple independent provider relationships) and must balance the required amount of data for care coordination with concerns about patient privacy and adhering to HIPAA. In addition to these clarifications, CMS could also publish voluntary best practices for attributing to providers to encourage alignment.

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 the clinician may bill (e.g., Tax Identification Number). We are concerned that the approaches and IGs suggested in the proposed rule set too low of a bar for attribution and who needs access to a patient's data to provide care and to help them manage their health. Instead, attribution should utilize a payer's current methods to identify providers with an established treatment relationship who have taken accountability for a patient's health care.

[19] https://www.caqh.org/core/attributed-patient-roster-operating-rules
[20] https://www.ahip.org/resources/ahip-response-to-ncvhs-request-for-public-comment

We recognize that as technology develops, the Provider Access API could be able to provide data to support real-time/interactive patient care. However, the data payers currently hold, and the current limits of technology mean that the Provider Access API will only be able to be used to exchange large files of retrospective claims-related data. These files will not be able to be easily parsed. As such, we do not believe CMS should propose policies in the future that would require payers to make an attribution prior to the first visit. The baseline expectation should be that payers will attribute members to providers who meet their current attribution rules. CMS could, in the future, allow payers to implement prospective attribution systems as the solutions become more mature. To implement a prospective attribution process, the industry needs to further develop this functionality. Prospective attribution methodologies often require the patient to name a provider and the provider to verify such relationship. However, as noted above, patients and providers frequently disagree over who has responsibility for their care. As such, the only way payers can prove a treatment relationship is through retrospective methods that rely on past claims. Allowing payers to use their current attribution methodologies will ensure patient data is only shared with providers who have a treatment relationship with that patient and the exchange meets the requirements of HIPAA.

AHIP believes that we must not compromise patient privacy as we move towards an interoperable health care system. Data sharing only should be with those who need the information to support treatment, payment, and operations purposes as outlined by HIPAA and the minimum necessary provisions. Until technology has advanced to a point where data can be easily segmented and CMS policies permit only some data to be sent to a specific party, attribution should be done in a way that protects the patient's privacy and confirms a relationship. Not all providers may need a patient's whole medical record or particularly sensitive information such as a history of treatment for substance use disorder and depending on its use that may be prohibited.

Payers should also have the ability to determine when a treatment (or other) relationship between a provider and patient is active or inactive, and when to "unattribute" a patient from a provider. Providers should not have unfettered access to the records of patients with whom they may no longer have a relationship. The attribution methods recommended by CMS seem to suggest that patients should be attributed to every provider who they have seen. However, a patient may see a provider for an isolated condition, wish to have a consultation for second opinion, or may see a provider and decide to use a different provider. Also, a patient may have seen a provider years ago and does not consider that there is a relationship with that provider anymore. CMS should clarify that payers also have the ability to unattribute a patient to a provider based on the impacted payer's current rules.

Recommendations

- *Finalize the proposal to allow payers to establish attribution rules based on their current methodologies.*
- *Clarify that attribution should be to an accountable provider with an ongoing treatment relationship and that a payer can terminate the attribution if there is no demonstrated ongoing relationship.*
- *Clarify and provide guidance on the intended level of attribution for access to a member's data.*

II. B. 3. B. Enrollee Opt Out

CMS proposes that all impacted payers would be required to establish and maintain a process to allow patients or their personal representatives to opt out of having the patients' data available for providers to access through the Provider Access API. CMS notes the agency does not intend to be overly prescriptive on how this opt out process should be implemented, but payers would be required to make this opt out process available and give all currently enrolled patients or their personal representatives a chance to opt out, before the first date on which patient information is made available via the Provider Access API. CMS proposes that impacted payers must maintain a process to allow patients or their personal representatives to opt out of data sharing, or if they have already opted out, to opt back in. The process for opting out and opting back in would have to be available before the first date on which patient information is made available via the API and at any time while the patient is enrolled with the payer.

AHIP appreciates CMS's efforts to protect patient privacy; 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 TPO processes for uses and disclosures. These processes should be covered by an entity's Notice of Privacy Practices. Establishing more cumbersome processes is counterproductive to the goal of ease of information exchange.

Additionally, regulations under 42 CFR Part 2 will be imminently aligning with HIPAA per the recent CARES Act and these regulations have yet to be made final. Moreover, there are existing processes at the state levels that differ in terms of including an opt-in or an opt-out. CMS setting a specific process here could be operationally challenging and could pose conflicts with other federal and state rules.

Rather than requiring a separate opt-out process, CMS should instead ensure that policies regarding the Provider Access API meet the requirements for TPO uses and disclosures under HIPAA. By aligning with HIPAA, CMS could allow all patients to benefit from the Provider Access API without undue delays. CMS should allow payers to use their existing attribution methodologies to ensure a provider has a treatment relationship with a patient to make necessary disclosures.

Recommendations

- *Do not require payers to implement an enrollee opt-in/opt-out process from allowing their data to be made available to a provider through the payer Provider Access API.*
- *Confine data sharing to physicians with a demonstrated accountable relationship.*
- *Should CMS require enrollee mediation, it should finalize and opt-out policy for the Provider Access API.*
- *Ensure the policies of the Provider Access API meet the requirements for a TPO disclosure under HIPAA rather than requiring separate consent processes.*

II. B. 3. C. Patient Resources Regarding the Provider Access API

CMS proposes to require payers to provide easy-to-understand information to their enrollees about the benefits to the patient of the Provider Access API requirements, their opt out rights, both for opting out of the data exchange and for opting in after previously opting out.

AHIP does not believe separate patient outreach and education is necessary if the data sharing under the Provider Access API is structured under HIPAA TPO allowances. Furthermore, providing separate information could be confusing to consumers and potentially conflict with information in the standard HIPAA disclosures.

Recommendations:

- *Withdraw the proposal to require payers to provide separate information to consumers on the Provider Access API.*

II. B. 3.d. Provider Resources Regarding the Provider Access API

CMS proposes to require payers to develop non-technical and easy-to-understand educational resources for providers that explain how they can request patient data using the payer's Provider Access API.

AHIP agrees that impacted payers should notify providers in their networks about the existence of the new Provider Access API, to ensure understanding of the availability of this resource and how to access it. However, CMS neither defines the term "educational resources" nor articulates the distribution method. Furthermore, impacted payers will not be able to provide much guidance on how providers could use the Provider Access API as the exchange is mostly intended to be with the EHR vendor, in order 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 or other vendors 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:

- *Clarify that the educational responsibilities of impacted payers entail 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.*

II. B. 4. A. Extensions and Exemptions for Medicaid and CHIP FFS Programs

CMS proposes a process through which states may seek an extension of and, in specific circumstances, an exemption from, the Provider Access API requirements if they are unable to implement these API requirements by the proposed effective date of January 1, 2026.

We support CMS's proposal to provide an extensions or exemptions process for the state Medicaid agencies operating FFS programs. States are experiencing and will continue to experience severe repercussions because of COVID-19 including impacts on their economies, unemployment rates and fluctuating Medicaid enrollment. In addition, states will be focusing significant attention and resources on conducting eligibility redeterminations for virtually all Medicaid enrollees well into the second quarter of 2024. However, we note that health plans with

which the states contract to deliver all or portion of their Medicaid programs are also under considerable financial strain due to downward pressure on their rates from the states, and many Medicaid plans will have roles in conducting outreach and education with Medicaid enrollees to ensure continuing coverage through the redeterminations process. 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 subsequent redeterminations and should be afforded the same latitude as the states.

CMS should also permit extensions and exemptions for MAOs as well as integrated Dual eligible special needs plans, especially if CMS does not finalize a phased-in approach to implementation. These payers are facing the challenge of unwinding current flexibilities implemented due to the public health emergency and are also facing significant requirements in coming years as proposed in the CY2023 MA and Part D proposed rule.

Recommendation:

- *Finalize an extensions and exemptions policy for Medicaid and CHIP FFS programs for the Provider Access API.*
- *Clarify that a state can request a second extension, if circumstances warrant, in the following year rather than seeking an exemption from the start.*
- *Monitor proactively 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.*
- *Create an exceptions and exemptions process across all APIs for both states and Medicaid managed care plans, including dental insurers that provide coverage to Medicaid managed care enrollees.*
- *Establish both an exception and an exemption process across all APIs for all impacted payers.*

II. B. 4. B. 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 implementation would pose significant barriers.

We agree with CMS that an exceptions process is warranted to ensure implementation of the API by QHPs would not result in consumers having few or no plan options in certain areas. We also support consistency of this policy with that of the one previously provided under the Patient Access API in the Interoperability final rule. However, as noted above, we believe impacted payers of all types may have difficulty implementing these extensive requirements.

Recommendation:

- *Implement an exceptions process for certain QHP issuers for the Provider Access API.*
- *Establish both an exception and an exemption process across all APIs for all impacted payers.*

II. C. PAYER TO PAYER DATA EXCHANGE ON FHIR

II. C. 2. Proposal To Rescind the CMS Interoperability and Patient Access Final Rule Payer to Payer (P2P) Data Exchange Policy

Due to implementation concerns, CMS proposes to rescind the payer-to-payer data exchange policy previously finalized. Instead, CMS proposes a new policy to require impacted payers to implement and maintain a P2P API using the FHIR standard.

We appreciate CMS recognizing our previous concerns that the previously finalized payer-to-payer exchange policy remains operationally infeasible at this time due to both unresolved policy issues as well as a lack of mature technical standards. While we support the shift in vision to using an end-to-end FHIR-enabled API to share some information between payers, we believe there are several key technological and infrastructure challenges that must be resolved prior to implementation.

First, we continue to question whether payers are the best stakeholders to hold what is, essentially, a patient's longitudinal health record. Second, we believe that a national network such as the TEFCA is a precursor to being able to share this magnitude of data efficiently and safely in an environment where claims and administrative data can be obtained from the payers, and clinical information can be best obtained from the providers by third-party entities that can support personal health records.

Instead of finalizing the new proposal, CMS should work with stakeholders to resolve the remaining technical dependencies and support implementation of the FAST solutions (e.g., payer directory) to enable scaled exchange via FHIR-enabled APIs. CMS should consider allowing the implementation of a P2P data exchange policy to happen on a voluntary basis to resolve the operational issues. Once that occurs, CMS should focus this exchange on sharing prior authorization information among payers, but only after the PARD API is implemented successfully. Finally, CMS should consider ways in which to restructure the aggregation of consumer information for personal health record purposes within the context of a national network.

Recommendations:

- *Finalize the proposal to withdraw the payer-to-payer exchange policy, but do not replace it with a new policy until further policy and operational concerns can be addressed.*
- *Work with ONC to develop a future-looking approach to allow consumers to direct the sharing of claims data with third-party entities via a national exchange.*

II. C. 3. A. Payer-to-Payer API Technical Standards

CMS proposes that beginning January 1, 2026 (and for Medicaid managed care plans and CHIP managed care entities, by the start of the rating period beginning on or after January 1, 2026, and for QHP issuers on the FFEs, for plan years beginning on or after January 1, 2026), impacted payers must implement and maintain a payer-to-payer (P2P) API that is compliant with the same technical standards, documentation requirements, and denial or discontinuation policies as the Patient Access API requirements.

The comments above notwithstanding, AHIP and its members support CMS naming, not recommending or requiring, the FHIR standards and associated IGs for the P2P exchange to encourage uniformity. We further recommend that a specific version of the IG be named as a floor and that a formal standards version advancement process (SVAP) be developed similar to the ONC SVAP process. This will give the industry and HL7 the opportunity to continue refining, testing, and deploying new versions yet ensuring the industry implements these policies in a consistent manner.

The proposal also includes use of the FHIR Bulk Data Access standard, which does 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 P2P API is adequately captured in the standards and IGs.

Recommendations:

- *Name not only the specific standards but also the specific IG versions as a floor and create a standards version advancement process.*
- *Ensure IGs are created and approved as part of a fair and transparent process that is ANSI accredited and does not require a fee to comment or participate.*
- *Adopt new versions only after sufficient time for testing, implementation, evaluation, refinement, and public input.*
- *Clarify the mapping of specific API functionalities to specific IGs as some functionalities do not appear to be captured in the IGs and some elements overlap in the IGs (e.g., USCDI CORE or PDex).*

II. C. 3. B. Payer-to-Payer API Data Content Requirements

CMS proposes to require impacted payers to implement and maintain a FHIR-based P2P API to exchange all data classes and data elements included in a content standard adopted at 45 CFR §170.213 (currently USCDI version 1), claims and encounter data (excluding provider remittances and enrollee cost-sharing information), and prior authorization requests and decisions that the payer maintains with a date of service on or after 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 API and data exchange proposals in this rule, we think CMS should reconsider which information is best to flow through which API and how the APIs will interact.

Interoperability holds great promise in allowing health insurance providers to facilitate better care for members and to take a more active role in care coordination. The P2P API specifically provides the opportunity to diminish potential disruptions for consumers changing plans and to help ensure continuity of care. However, sharing large amounts of unnecessary data can have the opposite effect; health insurance providers will have to ingest, store, and keep secure large amounts of irrelevant information making it harder to identify the facts necessary to effectively deliver benefits and care. We believe specific changes could be made to the P2P API policies to improve feasibility, minimize implementation burden, and increase the effectiveness, accuracy, quality, and utility of the data.

The focus of the P2P API should be on sharing information that will facilitate the consumer's transition from one impacted payer to the next or to support coordination of care and services between concurrent payers. The P2P API should facilitate the sharing of information that could assist an impacted payer in streamlining the onboarding of an enrollee that could speed new approvals or coordinating care when a patient has concurrent payers. To support this, CMS should focus the use of P2P API to a subset of key coverage, clinical, demographic, claims, and encounter data exchanged in a standardized form and format, which can be easily integrated into another payer's systems. We strongly encourage CMS to consider what set of information is minimally necessary for consumers to achieve smooth transitions between payers or coordination between payers and narrow the payer-to-payer exchange requirements to that information set. Doing so will greatly simplify and hasten efficient and effective implementation of the requirements and increase its utility. We also note that industry solutions are already being developed to better facilitate coordination of benefits between providers and these solutions could prove to be better address industry needs. We encourage CMS to continue to monitor and enable the state of technical innovation in this area.

In addition, CMS should also separate the goal of creating longitudinal consumer health records from the goal of supporting consumer transitions between payers. We believe CMS should shift its approach to ensure that any large-scale exchange of consumer data (e.g., full clinical and claims records) is consumer-mediated and results in easy and meaningful access to comprehensive consumer data. Consumer data beyond that which is needed for care coordination among payers is, and should remain, a component of the Patient Access API rather than the payer-to-payer exchange.

It is also important to note that in many cases the consumer (former enrollee) would not want certain sensitive data to be shared between payers, and that such choice should be respected. This would require development of segmentation techniques and be incorporated into the IGs.

Prior Authorization Data

We agree there is some value in sharing information on pending and active prior authorizations via the P2P API. This data could speed the time to approval by a new payer by minimizing the information the new payer may need to make its own determination of coverage. However, payers have different prior authorization policies and requirements, and the fact that a prior authorization was pending or completed by a previous payer may but does not necessarily add value to the new payer.

While we support the exchange of this information using FHIR-enabled APIs, we note that PDex IG STU2 that includes the prior authorization profile to share prior authorization information is not yet published. As noted in our responses to the Patient Access API and Provider Access API, we believe some of the data elements CMS proposes to include across the APIs are not feasible. As with the Patient Access API and Provider Access API, CMS should only require the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date. Information on the units and services consumed to date would have little benefit for a new payer as the patient would still be entitled to the full benefits provided by their new payer.

However, unlike in the Patient Access API and Provider Access API, where it would be redundant to have clinical information already included, we do support the sharing of the supporting documentation through the P2P API, as the next payer could potentially use that information to support their decisions about a subsequent prior authorization, if the new payer has the same. CMS should leverage the P2P API to facilitate the exchange of documentation to support a previous prior authorization. However, as noted above, payers will have variances in requirements for prior authorization policies due to differences in covered benefits, network composition, formularies and requirements, and medical review criteria compared to the former payer.

Recommendations:

- *Reconsider which data should flow through which API so that efficiency can be achieved and redundancy of, and inconsistencies in the data can be avoided.*
- *Require only the approved number units (such as approved visits) for a specific prior authorization and not the units and services used to date.*

USCDI

CMS proposes to require impacted payers to share all data elements included in the USCDI standard (e.g., lab results – version 1.0) in both the Patient Access API and in the P2P API. However, health insurance providers do not commonly collect the information contained in the USCDI. These data elements are commonly derived from EHRs which are installed and used by the treating providers, and to which plans generally do not have access. While some clinical information is furnished to health insurance providers (sometimes in electronic format) for administrative purposes, claims processing, prior authorization, quality reporting, risk adjustment and utilization management, such information would not be helpful for continuity of care when a consumer changes health insurance providers. This will likely result in duplicative and inconsistent information, when compared with the information maintained by the health care provider in an EHR. In fact, the only clinical information that payers collect, and that AHIP members believe could be relevant to the next impacted payer, are clinical findings associated with pending and active prior authorization determinations. For example, it would be helpful for the new payer to know the results (e.g., labs or images showing initial therapeutics were ineffective) of a prior step therapy approach.

In addition, the clinical information shared by providers with payers is not received or stored in a structured way that can be efficiently consolidated and shared from payer to payer. Most payers receive unstructured data with file formats such as PDF or JPEG because the claims attachment standard has never been finalized (although this could change based on current rulemaking). Currently, 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 they could, 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.

Here again it is important to note the need to follow minimum necessary provisions from the HIPAA privacy rule, and if the request is not consumer-mediated, only request and/or exchange the minimum data necessary for the intended purpose.

Recommendations:

- *Remove the requirement that impacted payers share all clinical information as represented by the full USCDI v1 and focus on the clinical information that has been received in standard, electronic structured format related to prior authorization.*

Claims and Encounter Data

CMS proposes to require payers to include claims and encounter data (not including cost information) that the payer maintains with a date of service on or after January 1, 2016, as part of the P2P API.

If the payer-to-payer exchange is focused on information that would assist another payer with easing consumer transitions of care, some encounter data could be helpful, but a consumer's entire claims or encounter history would not. For example, in the future, it may be instructive to share the ICD-10-CM codes associated with social determinants of health. It could, as another example, make sense to share immunization records already covered and documented by the payer, even if that information might be more accurately available from the patient's provider or from a state immunization registry. However, sharing full claims history is fraught with technical challenges and poses a significant administrative burden. Unreasonably large and unwieldy data sets will be hard to review for relevant information and integrate into the new payer's systems. CMS could reduce some of this burden by clarifying that denied claims do not need to be sent.

We believe the goal of achieving a longitudinal health record to support a person's health management and clinical care, while laudable, is a separate and distinct consumer use case that involves the health information about a consumer that exists primarily in different EHRs, the original source of such data, and thus should not be required as part of the payer-to-payer exchange. While we believe impacted payers have a role to play in supporting and contributing to longitudinal health records, we do not believe sharing this extensive claims-based and clinical data through the P2P API is the most efficient, effective, reliable or comprehensive method to achieve that objective. It should not be incumbent on payers to collect and store information for a consumer's lifetime (passed from one payer to the next). We additionally note that that these provisions do not currently apply to all health care payers a patient may encounter, including Medicare FFA and Defense Health Services or the Veteran's Administration.

We believe the creation of a longitudinal health record should focus on supporting consumer-centered and mediated approaches and personal health records resources, which is better suited as a component of the Patient Access API. Impacted payers have already made full-scale claims data available to consumers through the Patient Access APIs. Through this technology, a consumer can already access their data and share it with an app of their choosing. Further, they can do the same with their clinical information based on a combination of ONC and CMS requirements. Such data could be housed by an entity that can integrate claims and clinical data, along with other sources such as patient-reported outcomes, to create actionable and easy-to-use information for consumers, providers and others. A more streamlined solution, such as a patient-centered data home, should be part of a longer-term roadmap developed in collaboration with the industry.

Moreover, ONC and the RCE have made significant progress towards launching TEFCA, which includes IAS as a voluntary component of the initial launch. Once TEFCA is FHIR-enabled, QHINs could connect to these APIs and serve as a single point of entry for consumers, to obtain their data in a private and secure manner without duplicative requests to each payer and provider. In addition, each stakeholder could maintain control over their subset of data, allowing for data to be corrected or updated if needed.

Recommendations:

- *Exclude longitudinal claims and encounter history from the P2P API.*
- *Work with industry on a subset of key claims information to share via the payer-to-payer exchange to support coverage transitions.*
- *Continue its policy of enforcement discretion until the standards and IGs needed to support the current payer-to-payer data exchange regulations are sufficiently mature and fully tested.*
- *Work with ONC and its RCE to prioritize within TECFA, QHINs leveraging impacted payer and provider APIs for the individual access services use case.*
- *Work with ONC and industry stakeholders to develop a longer-term FHIR roadmap including a patient-centric data home that permits information to be collected, stored, and integrated from across the health system on behalf of a patient to be both efficient and effective.*

Request for Comments on Honoring a Previous Payer's Prior Authorizations

While CMS does not propose at this time to require payers to review, consider, or honor the active prior authorization decision of a patient's former payer, the agency notes its belief that payers may gain efficiencies by doing so, and seeks comment on the possibility.

We agree that the availability of information on prior authorization decisions from a previous payer could reduce burden and promote continuity of care. However, 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, a payer's benefit and coverage policies, and potential changes in the patient's comorbidities or health status after enrollment in the new payer. 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. If there has been progression in a person's disease, a treatment may no longer be clinically appropriate. Moreover, a new reviewer may catch evidence of a contraindication or negative side effect or find that treatment is no longer consistent with clinical guidelines. Finally, clinical guidelines are continually evolving, and recommended care could change during a patient's treatment.

CMS should not propose requirements for a new payer to honor a previous payer's decisions. However, if CMS does propose such requirements, they should be only in certain situations where a delay could impact a patient's outcomes and for certain conditions. Additionally, any requirement should be time-limited and not extend beyond 30 days and the

new payer should retain the ability to review the previous payer's decision during those 30 days to make its own decision thereafter.

II. C. 3. C. Identifying Previous and Concurrent Payers and Opt In

CMS proposes that all impacted payers must develop and maintain processes to identify a patient's previous and/or concurrent payer(s) and to allow patients or their personal representatives to opt into payer-to-payer data exchange (both with previous and concurrent payers) prior to the start of coverage. Payers would also need similar processes for current enrollees who are continuing enrollment with their same payer to ensure those enrollees can opt in prior to the data being shared through the API.

We believe that several feasibility and infrastructure issues would need to be resolved prior to implementation of the P2P API. For instance, it is not clear from the proposed rule how impacted payers are to identify a patient's previous and/or concurrent payers. CMS proposes directly collecting this information from the patient but does not specify whether that could be on paper, electronically, or through the API. Our comments reflect an assumption that for this to be feasible, the collection will have to be electronic and automated. As detailed below, any of these forms would require significant updates to current processes, but both the electronic and API options would also require updates to either the X12 transaction or the FHIR IGs. For example, the X12 834 enrollment transaction does not currently carry prior payer information, complete information on concurrent payers, member ID data, or member consent information necessary to support P2P data exchange during QHP enrollment. Moreover, unless this information can be collected in a uniform, structured manner it is not likely to be complete enough to accurately identify the previous payer. In addition, payers will need to find ways to locate each other's digital endpoints, calling again for the need to have a national API endpoint directory. As outlined below, in the absence of the NDH, this will be a burdensome task.

There are also situations where a patient begins the enrollment process but does make the binder payment to effectuate the coverage. CMS should clarify the process to ensure that prospective or potential payers are not requesting a patient's data. This could result in payers holding unnecessary data and risks creating superfluous copies of a patient's data which could pose a privacy risk.

Another key challenge will be accurate patient matching. Incorrect matches jeopardize not only a person's privacy but could pose a safety risk if information about current treatments or prior authorizations are not correct. CMS proposes an attestation process to overcome legal barriers, but an attestation will not resolve the risks of an inaccurate patient match.

<u>Lack of Infrastructure to Locate Information on Past and/or Concurrent Payers</u>

Before requiring implementation of the P2P API, CMS should first resolve the technological infrastructure dependencies by further investing in the HL7 FAST Accelerator to address challenges such as the lack of a national payer API endpoint directory.

Currently, there is no national system of payer identification or common payer identifier. While the National Association of Insurance Commissioners (NAIC) identifier is sometimes used, it is not a nationally recognized standard. A lack of standardized payer identifiers will make this data element difficult to operationalize and could introduce errors and confusion.

The proposed rule implies that payers should collect the name of the previous and/concurrent payers directly from the patient during enrollment or at other points. While such a system may work in certain regions of the country where there are a limited number of payers and most patients are transferring between a small group, it is not scalable nationwide. Patients may provide incomplete or inaccurate information or may not have retained documents such as their past insurance cards to allow them to easily find the name of their payer. Second, there is no system for payers to easily retrieve each other's digital endpoints. As noted above, we were encouraged by CMS's recent RFI on the establishment of an NDH. We believe that creation and implementation of the NDH will be essential to successful implementation of the P2P API. The Interoperability final rule and the Information Blocking final rule represented important steps toward improved information sharing. However, sharing data over the pathways created by these rules depends on payers and providers being able to find each other's digital endpoints. Thus, digital endpoints are essential to the implementation of requirements such as the payer-to-payer data exchange.

The NDH will be essential to implement the P2P API. A centralized source with information on each payer's digital endpoint is needed to prevent each payer from individually having to ask other payers how to reach them. To avoid unnecessary burden and to meet the goals of the payer-to-payer data exchange, we need a national solution that includes information on all stakeholders, including their digital endpoints.

Recommendations:

- *Create a public-private partnership between the federal government, providers, payers and solutions vendors to develop a federated NDH model.*
- *Leverage the NDH and TEFCA to collect and share information on payers' digital endpoints to allow implementation of the P2P API.*

<u>Patient Matching</u>

It is essential that patient records are matched correctly to maintain privacy and avoid safety issues. Patient matching rules will be particularly critical where a consumer no longer has credentials to electronically access their health information from their former health insurance provider or other entity that holds their health data. **Before requiring implementation of the P2P API, CMS should work with ONC to support the development of solutions that could facilitate patient matching.**

We appreciate ONC's work with standards development organizations and other stakeholders on the Project US@ ('Project USA') Technical Specification Final Version 1.0., which is a unified, cross-standards, health care specification that could be used across industry for representing patient addresses (mailing, physical, billing, etc.) to improve patient matching. We are also monitoring the new CARIN Alliance Digital Identity Initiative sponsored by HHS, which is aimed at addressing, patient matching within TEFCA and beyond. However, such efforts have not fully resolved the difficulties of patient matching; thus, we encourage CMS to consider this in determining the way the payer-to-payer data exchange is structured.

Recommendations:

- *Resolve the technological infrastructure dependencies by further investing in the HL7 FAST Accelerator and ONC's work to facilitate patient matching.*
- *Ensure patient matching standards are mature before implementation of the P2P API or structure the exchange to minimize the need for patient matching.*

Process to Collect the Necessary Information

CMS notes that in some cases, a payer may provide coverage retroactively necessitating the collection of permission to exchange data through the P2P API and identification of a new patient's previous and/or concurrent payer(s) prior to the date the enrollee's enrollment is processed.

There are a number of logistical challenges to collecting such data at enrollment. Currently, enrollment is done electronically through either the X12 834— Benefit Enrollment and Maintenance transactions, as required by HIPAA, or through the processing of paper forms or other formats such as PDFs or spreadsheets. Thus, there is currently no consistent way to modify the collection of the necessary data. The use of paper forms not only risk inaccurate or incomplete data to successfully identify the payer and the enrollee but also would be prohibitively burdensome. Moreover, there would be logistical and regulatory challenges to modifying the existing enrollment forms. CMS should work with stakeholders to develop processes (e.g., modify Healthcare.gov and the enhanced direct enrollment process) to collect the new necessary information, including member consent, prior payer information and prior payer member ID data, in the application process and X12 834 transaction. There may be an opportunity to work with X12 to leverage the X12 834 in Loop 2750 to handle the opt-in and prior/concurrent payer, but this would need to be either retrofitted into the version 5010 on an emergency basis or quickly included in the version 8020 before it goes into rulemaking.

CMS should also work with states to implement a consistent solution across Medicaid enrollment processes to avoid inconsistencies in what data is collected and how. CMS proposes that collection of the opt-in and information on prior and current data would be collected by state Medicaid and CHIP agencies and provided to payers who are under contract to the state. CMS should provide guidance and best practices to the states to avoid the creation of over 50 formats and processes.

In the meantime, we urge CMS not to finalize any policies that require the collection of data to support the payer-to-payer data exchange at enrollment and instead allow outreach to patients through tools they currently leverage, such as existing payer portals. **A safe harbor for payers permitting members to enroll in P2P API data exchange when they log in to their online member account would allow payers to use proven processes and technologies to collect the necessary information from patients.** Existing portals, which patients are familiar with, could be leveraged to allow the patient to opt-in to the data exchange through their portal and provide standardized information about their previous and/or concurrent payers to complete the transaction. Such a patient-driven approach could streamline the opt-in process and resolve several of the technical challenges around patient matching and identifying other payers. Using existing portals could also allow payers to follow-up with patients to correct errors or to collect additional data if records cannot be located.

Recommendations:

- *Withdraw policies that would require collection of the data needed for the P2P API data exchange at enrollment.*
- *Work with stakeholders to modify enrollment processes to serve as a potential data collection method.*
- *Allow payers to utilize existing member communication channels such as online portals to collect the necessary data and consent for the P2P API exchange as an option.*

Allowance for a Soft Launch

CMS recognizes some payers may want to have a soft launch, rolling implementation, or pilot for their P2P API before the proposed compliance date. Therefore, CMS is tying the proposal to require payers to gather permission from currently-enrolled patients to the proposed compliance date, January 1, 2026, rather than when a payer implements their API.

While we appreciate that CMS recognized the need for a soft launch of the P2P API, we urge CMS not to finalize several of the P2P API policies proposed in this rule. As noted above, there are significant infrastructure needs such as maturation of the standards and IGs and resolution of issues like directory and patient matching that must be addressed first in order to get to implementation. CMS should allow payers to develop pilots of the P2P API as strategies to resolve the remaining technical dependencies and support implementation of the FAST solutions to enable scaled exchange via FHIR-enabled APIs. A demonstration of the maturation of the infrastructure should be a precursor to the API becoming a requirement. Moreover, the initial focus should be on the other use cases that are further along and less complicated. Additionally, CMS should continue to monitor and enable the state of technical innovation in this area and ensure regulatory flexibility to support technical developments.

Recommendations:

- *Allow payers to pilot the concept on a voluntary basis before re-issuing a proposed rule requiring the P2P API focusing on sharing prior authorization information among payers.*

Patients Enrolling after the Compliance Date

CMS proposes to require impacted payers to have a process for members to opt-in to this P2P API at any time after the start of coverage, or if they have already opted in, to opt out, at any time.

Payers would establish a process for allowing members to opt-in to this exchange. But while payers could conceivably create a process to allow members to opt out of the exchange if they have opted in, we caution that CMS's proposed timelines mean the data exchange will occur shortly after the patient opts-in to the P2P exchange. Once the data is shared while the patient was in opt-in mode, it will not be possible to "unshare" it. CMS should clarify that payers are not expected to ask the receiving payer to delete files after they have been shared. This policy also seems to suggest that there is ongoing data exchange rather than a one-time exchange with a previous payer. While a second exchange at 90-days post disenrollment may be prudent to capture claims run out, we do not believe that further requests should be entertained beyond that point for previous payers. The only ongoing exchange should be for patients with concurrent

payers. CMS should clarify that the opt-out policy is to allow patients with concurrent payers to stop the continuing quarterly data exchanges and allow payers to limit the opt-out for new exchanges to cases where the data exchange has not yet occurred.

Recommendations:

- *Clarify that payers are not expected to delete files already provided through the API if a patient opts-out after the data exchange has occurred.*
- *Clarify that the opt-out policy will apply to patients with concurrent payers to stop the continuing quarterly data exchanges.*

Request for Comment on Incorporating Proposed Requirements into the FFE QHP Enrollment Process

CMS solicits comments on incorporation of the proposed requirements into the FFE QHP enrollment process.

The FFE facilitates enrollment in QHPs through the centralized *Healthcare.gov* website. As noted above, the current X12 834 enrollment transaction does not currently carry the prior / concurrent payer information, member ID data, or member consent information necessary to support P2P data exchange during QHP enrollment. CMS should work with stakeholders to update processes on *Healthcare.gov* and through the Enhanced Direct Enrollment process to collect this consent, prior payer information, and prior payer member ID data in the QHP application process and X12 834 transaction. In the meantime, CMS should allow payers to utilize current processes such as member portals to collect the necessary information. Payers should not be required to seek this consent outside of an online experience. This reduces burden and streamlines the experience for members.

Recommendations:

- *Work with stakeholders to revise enrollment processes to support participation in the P2P exchange.*
- *Provide through the FFE additional information on the X12 834 transaction to facilitate implementation of these requirements by QHP issuers.*

<u>Request for Comments on Changes to Allow for an Opt-Out Process</u>

CMS proposes an opt-in approach to data exchange through the P2P API. However, CMS seeks comments on regulatory changes that could allow for an opt-out process instead.

As noted above, there is not a current mechanism that would allow a new payer to identify a patient's previous payer or for the previous payer to proactively identify a patient's new payer. Therefore, payers will need patients to opt-in to the P2P exchange and provide information on their previous payers. Without information from the enrollee, the new payer will not know who the previous and/or concurrent payers are. An opt-out process would require solutions for accurately and consistently collecting data on previous and/or concurrent payers. CMS should work with stakeholders to resolve the current challenges to collecting the necessary data such as updating enrollment forms and working with X12 to update its 834 transaction. Moreover, if the data shared is the entire claims history to approximate a longitudinal health record, enrollees should have the choice whether or not share this information. If the P2P API was confined to the

sharing of prior authorization information to support coordination in benefits and care, then these services would be part of TPO and would neither require an opt in nor an opt-out.

II. C. 3. D. Requesting Data Exchange From a Patient's Previous and/or Concurrent Payer(s) and Responding to Such a Request

CMS proposes to require impacted payers to request a patient's data from their previous and/or concurrent payer(s) no later than 1 week after the start of coverage. If after the start of coverage, a patient opts into the data exchange or provides previous and/ or concurrent payer information, or requests data exchange for another reason, CMS proposes that the current payer would be required to request data from the previous and/or concurrent payer(s) no later than 1 week after the payer has the necessary permission and information.

While we agree that information should be requested in a timely manner to facilitate transitions in coverage, we are concerned about the feasibility of the new payer requesting the data within one week after the start of coverage or no later than one week after the patient makes the request (if after the start of coverage). Payers will be dependent on information received from the patient to operationalize a request through the P2P API. Given the current structure of the P2P API, this will require patient matching, and impacted payers may have to go back to the enrollee for clarification if information in incomplete or inaccurate. Additionally, until the NDH or alternate solution is operational, payers will need to figure out alternative ways to contact each other for information on the digital endpoints necessary to complete the request. CMS should clarify the timeframes to ensure feasibility. Moreover, there may be mapping or coding changes necessary to accommodate the other payer's API. Even if both payers are using the recommended IGs, the new payer will need to deploy staff to read the posted API documentation and determine if changes are necessary.

CMS should revise the proposal to allow that impacted payers two weeks after the start of coverage to complete the exchange even if the patient has provided all necessary information, that information is correct, and the payer endpoints are publicly available. If the payer endpoints are not publicly available or accurate information on a previous payer is not available, payers should only be required to make reasonable efforts to complete the data exchange. In this case, finding the endpoints or previous payer information would not be automated and would require humans to contact the former payer and determine the appropriate digital endpoints or follow up with the member for more information. This would be particularly challenging given the January 1 start date for the majority of plans covered by this proposed rule.

Recommendations:

- *Collaborate with ONC to encourage industry adoption of the HL7 FAST solutions for, at minimum, identity resolution, security, and directory.*
- *Modify the requirement for the exchange to be completed within two weeks instead of one week of coverage or one week after receiving the request.*
- *Clarify that if the necessary information such as accurate information on the previous payer and their digital endpoints are not available that the new payer only needs to make a reasonable effort to complete the data exchange.*

- *Alternatively, withdraw the timeframe proposed and work with stakeholders to determine a feasible timeline given the current limits of the technical infrastructure and data accuracy needs.*

Accommodations for Additional Data

CMS notes it envisions the payer-to-payer data exchange being a one-time transaction between payers, but also wants to allow enrollees to request subsequent data exchange given outlier situations or the availability of additional data. CMS notes the agency considered requiring data to be sent to the new payer within 1 week of receiving any additional data but did not propose this due to the associated burden. CMS instead seeks comments on such a policy.

We support CMS's current vision of the P2P being a one-time transaction. Requiring the previous payer to reconcile whether the patient opted in for the P2P API and the receipt of new data on a rolling basis would be overly burdensome for little benefit. Generally, most claims run out occurs within 90 days, suggesting at most two data transfers would be necessary for overwhelmingly complete data.

Recommendations:

- *Permit up to two data sharing requests with each previous payer within the P2P API.*
- *Modify the timeline to two weeks instead of one week.*

Authorization and Authentication Protocols

Impacted payers would be required to use the OpenID Connect authorization and authentication protocols to authenticate the identity of the requesting payer. CMS proposes to require the requesting payer to include an attestation with the request for data affirming that the patient has enrolled with the requesting payer and has opted into the data exchange in a manner that meets the necessary legal requirements.

As noted above, if the exchange is confined to TPO, then an attestation and an opt-in would not be necessary. Moreover, a better process for obtaining an opt-in would be to allow payers to use their existing portals for both payers to request the exchange on one side and accept the data on the other. Using current portals could streamline the process for a patient to opt-in to the P2P data exchange, provide the necessary consent and information, request the exchange and ensure user authentication and authorization. In addition, CMS should not move forward without naming the standards, IGs, and versions. Having said that, we urge the agency to work with HL7 to diminish the costs associated with authentication in PDex by testing the opportunity to rely on UDAP. Specifically, there is a requirement to generate two tokens which doubles the cost of implementing the security transaction while offering no additional benefits. Utilizing UDAP would remove such financial burden and "future proof" the designs.

Beyond the technical issues of issuing the necessary tokens or credentials, payers may have additional privacy or security protocols to allow access to patient data. While CMS proposes an attestation process, the proposed policies do not allow much time for payers to exchange this attestation. Some payers may have risk or security policies that require a wet ink signature to allow access to data. CMS should consider such data security concerns when finalizing processes and timelines for compliance with the exchange.

In addition, there may be complications from the recently proposed Claims Attachment Standards rule and the attestation CMS proposes in this rule. CMS should work with HHS to clarify if FHIR can be used to send the attestation form or whether the X12 transaction would be required or permissible.

Recommendations:

- *Collaborate with industry stakeholders to resolve ongoing questions on the best processes for user authentication and authorization.*
- *Work with HHS to ensure there is no conflict between the attestation policy proposed in this rule and the Attachment Standards proposed rule.*

Timeframes to Respond

CMS proposes that the previous and/or concurrent payer, if an impacted payer, would be required to respond to a current payer's request, if it meets the requirements, within 1 business day of receipt. However, CMS seeks comment on whether payers could accommodate a shorter period for the data request at the start of coverage, such as 1 to 3 business days, and whether payers need more than 1 business day to respond to a request.

We concur with CMS that it is appropriate to overtly offer enrollees the option of bringing their claims information and prior authorization decisions 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. Until the NDH is operational and a system for efficient data sharing has been established, it is not feasible for payers to respond within one business day of a request. At this time, payers are not able to easily find each other's digital endpoints to make the necessary connection. Until the NDH is a reality, payers will need time to conduct outreach to the new payer to gather the information necessary to connect.

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.

Recommendations:

- *Revise the proposal to require payers to respond to a request within one business day to three business days if all needed data and connections are available or within a reasonable time period if additional outreach is necessary.*

Quarterly Data Exchange for Concurrent Payers

CMS proposes that when a patient has concurrent coverage with two or more payers, the impacted payers must both send and receive the patient's data available to every other concurrent payer at least quarterly.

We support CMS's proposal to require quarterly data exchanges. Regular data exchanges will allow both payers to be aware of key events and changes in the patient's clinical history to facilitate care and improve coordination of services.

Recommendations:

- *Finalize the proposal to require quarterly exchanges of data between concurrent payers.*

Responding to Non-Impacted Payers

CMS notes that if a previous and/or concurrent payer is not an impacted payer, they would not be subject to these proposed requirements and, therefore would not be required to send data through the P2P API. CMS clarifies that impacted payers would meet their obligations under this policy by competing their part of the transaction (i.e., requesting the exchange or responding to a request) rather than through a successful exchange with a non-impacted payer.

As this rule is only applicable to plans in federal programs, it would be inappropriate to attempt to require non-impacted payers to respond. To do so, CMS along with the Departments of Treasury and Labor would need to issue companion rulemaking.

Recommendation:

- Do not attempt to require non-impacted payers to respond to P2P requests.

II. C. 3. F. Data Incorporation and Maintenance

CMS proposes that any information received by an impacted payer through this data exchange must be incorporated into the patient's record with the new payer but notes that the data do not need to be maintained for unenrolled patients any longer or differently than they do under current law, regulation, or policy.

We appreciate CMS aligning with existing law, regulation, and policy. For longer access to data, CMS should work with the industry to develop the concept of a patient-centric data home that permits information to be collected, securely stored, and integrated from across the health system. CMS should explore ways to leverage the Patient Access API and TEFCA to support longer-term data maintenance and storage rather than treating impacted payers as data warehouses.

In addition, the new payer will have limited ability to validate the data received from another payer. Thus, payers that use this data information to inform new care and treatment decisions should have some form of liability protection for errors in these data exchanges from another originator.

Recommendations:

- *Finalize the current policy and do not require payers to maintain data for unenrolled patients any longer than required by current laws, regulations, and policies.*
- *Explore ways to leverage TEFCA to support longer-term data maintenance and storage.*

II. C. 3. G. Patient Education Requirements

CMS proposes that impacted payers would have to provide educational materials regarding the P2P API to all patients at or before requesting opt in and at least annually.

All stakeholders, including payers and federal agencies, should play a role in patient education regarding data sharing. Opting into the payer-to-payer data exchange could allow for improved

transitions in coverage and help minimize any disruptions in care from coverage changes. Thus, we support the policy theoretically, but it should not be implemented until the P2P API can be restructured per our earlier comments.

Recommendations:

- *Align the requirements for impacted payers to provide education materials to enrollees with the implementation of a revised P2P API policy.*

II. C. 4. a. Inclusion of Medicaid and CHIP FFS

CMS proposes to require Medicaid and CHIP FFS programs to implement the Payer-to Payer API data exchange policies in this proposed rule.

AHIP supports the application of the P2P API requirement to Medicaid and CHIP FFS programs. However, we recognize that state Medicaid agencies are currently focused on redetermination, which is a tremendous effort and is resource intensive. We are concerned that states may not currently have the time and resources available to set up new processes such as the P2P API. We urge CMS to delay implementation of the P2P API until a reasonable amount of time after the completion of the redetermination process.

To support true interoperability between all payers and the intended goal of patients accessing and moving their longitudinal record throughout their healthcare journey, we recommend CMS explore ways to also include additional public payers in these APIs. In the preamble to the rule CMS indicates intent to ensure that people with FFS Medicare benefit from the policies prosed and seeks comment on how these proposals could apply to Medicare FFS. To accelerate interoperable data exchange, **we recommend that CMS develop an "AB2C" API, enabling Medicare FFS to share data with MA plans.** Although, this potentially could be accomplished through the existing Blue Button API with somewhat different privileges for payers than third party app developers.

We also urge CMS to align access to a new AB2C API with the ONC's emerging FHIR-enabled TEFCA. Making TEFCA the path for MA plans to access Medicare fee-for-service data would be a huge accelerator to TEFCA adoption overall while further accelerating the U.S. toward health data interoperability. This will enable MA carriers to serve beneficiaries better, improve health outcomes and ensure that the patient data MA carriers provide to patients and providers includes the patients' data from periods when they were beneficiaries of FFS Medicare.

We encourage CMS to work with the Department of Defense (DOD) and the Veterans' Administration (VA) to develop FHIR-based P2P APIs comparable to those proposed in this rule. We recommend CMS and ONC collaborate with the VA to develop and deploy a FHIR-based API to make data about the care received at VAMCs available to private plans that insure VAMC care recipients. Approximately 7 million veterans who receive care provided by Veterans' Administration Medical Centers (VAMCs) also have another source of public or private coverage. Improved data sharing between VAMCs and private payers will enable private payers to better serve veterans, who may face specific service-related health issues and have access to VA services tailored to veterans' needs.

Recommendations:

- *Delay implementation of the P2P API for FFS Medicaid and CHIP agencies and Medicaid Managed Care Organizations (MCOs) until a reasonable amount of time after completion of the redetermination process.*
- *Finalize the policy to require FFS Medicaid and CHIP programs to participate in the P2P API.*
- *Explore ways to facilitate data sharing across other payers including between FFS Medicare and (MA) organizations.*
- *Encourage the DoD and VA to also participate in the payer-to-payer data exchange.*

II. C. 5. A. Extensions and Exemptions for Medicaid and CHIP FFS Programs

CMS proposes a process through which states may seek an extension of and, in specific circumstances, an exemption from, the 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 state FFS agencies. States are experiencing and will continue to experience severe repercussions because of COVID-19, including impacts on their economies, unemployment rates and fluctuating Medicaid enrollment, as well as the significant and unprecedented allocation of time and resources to conducting Medicaid redeterminations. 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:

- *Finalize the proposal to establish an extensions and exemptions policy for Medicaid and CHIP FFS programs for the P2P API.*
- *Clarify that a state can request a second extension or exemption, if circumstances warrant, in the following year rather than seeking an initial exemption.*
- *Monitor proactively for systemic impacts on states that would impact their ability to implement such policies, such as a termination of the enhanced FMAP, and alter effective dates accordingly.*
- *Create an exceptions and exemptions process across all APIs for all impacted payers.*

II. C. 5. B. 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 implementation of the proposed rule's requirements would pose significant barriers.

We agree with CMS that an exceptions process is warranted to ensure implementation of the API by QHPs would not result in consumers having few or no plan options in certain areas. We also support consistency of this policy with that of the one previously provided under the Patient Access API in the Interoperability final rule. However, as noted above, we believe impacted payers of all types may have difficulty implementing these extensive requirements.

Recommendations:

- *Establish an exceptions process for certain QHP issuers to the P2P API.*
- *Establish both an exception and an exemption process across all APIs for all impacted payers.*

II. D. Improving Prior Authorization Processes

II. D.3.a. Prior Authorization Requirements, Documentation, and Decision (PARDD) API

CMS proposed the development and deployment of a new FHIR-enabled PARDD API to support coverage and documentation look-up as well as electronic prior authorization (ePA).

Prior authorization allows health insurance providers to promote safe, timely, evidence-based, affordable, and efficient care. Under the supervision of medical professionals, prior authorization can reduce inappropriate care by preventing unsafe or low-value care and targeting where care may not be consistent with the latest clinical evidence. Unsafe, low-value, or care that is not evidence-based can contribute to potential harm to patients and unnecessary costs. However, the prior authorization process can be burdensome to providers, patients, and health insurance providers. In 2018, stakeholders representing providers and insurers developed a Consensus Statement[21] recommending opportunities to improve the prior authorization process. Increasing the adoption of ePA was one of the major opportunities identified for improving prior authorization.

In 2020, AHIP launched the Fast Prior Authorization Technology Highway (Fast PATH) initiative to study the implementation of ePA and its potential to reduce the burden of the prior authorization process. The Fast PATH study found numerous benefits of ePA for providers. The results showed that ePA resulted in fewer phone calls and faxes and less burden and time spent related to prior authorization. Fast PATH also found that ePA made it easier for providers to understand if prior authorization was required, easier to understand prior authorization requirements, and easier to view prior authorization decisions.

A significant finding of Fast PATH was that experienced users benefited the most from implementing ePA. The results clearly showed that the more frequently a provider used the technology solution, the bigger the benefit the provider experienced in ease of understanding prior authorization information and reduced burden.

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 requirements. 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. Thus, **AHIP and its members support the concept of the PARDD API.**

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

Content and Technical Standards

AHIP supports naming not only the base standards but also the IGs. We further recommend that a specific version be named as a floor and that a formal standards version advancement process (SVAP) be developed similar to the ONC SVAP process. This will give the industry and HL7 the opportunity to continue refining, testing, and deploying new versions while ensuring the industry implements these policies in a consistent manner.

Having said that, as noted in the Patient Access, Provider Access, and P2P API sections of this letter, we have concerns about both the process and the maturity of the IGs. In particular, we have concerns about the operational challenges associated with implementing the prior authorization information given the lack of content and technical standards for prior authorization information such as denial/decision codes. Although CMS[22], X12[23] and CAQH[24] have developed reason codes and operating rules, there is not a single, comprehensive national standard that applies across all prior authorization modalities, payers and technologies. Another obstacle to effective implementation is the dependency on structured, 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 lack of interoperability, limitations in the automation, electronic process, and potential errors, which can create care delays and patient safety concerns. Moreover, there is a cohort of providers that were not included in the EHR Meaningful Use program (such as behavioral health providers) and due to limited financial and technical resources, equitable adoption of APIs for use across patient populations may be limited. As a result, there are significant challenges to adjudicating prior authorization requests through API interfaces without additional clinical data.

To ameliorate these challenges and allow stakeholders the time to successfully implement the necessary components and functionalities of the PARDD API, we recommend CMS implement the API in a staggered approach. For example, CMS could start with implementation of the HL7 Coverage Requirements Discovery (CRD) implementation guide to allow providers to determine if a prior authorization is required. CMS could then determine which of the HL7 Da Vinci Prior Authorization Support (PAS) FHIR IG or HL7 implement the Da Vinci Documentation Templates and Rules (DTR) IG is most mature. As of now, there is some concern that the DTR IG will take the longest to mature. However, all of these could be staggered over a 24-month period if each successor step scales quickly and efficiently. By doing so, CMS could allow the IGs to mature, and payers, providers, and EHR vendors to have enough time to build, test and implement their capabilities, and avoid frustrating providers by unnecessary variation in when a prior authorization request can be submitted electronically. CMS should, however, work with AHIP members and other stakeholders to determine the most logical order for implementing a staggered approach depending on the speed with which each IG matures.

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[22] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Reason-Codes-and-Statements
[23] https://x12.org/codes/error-reason-codes
[24] https://www.caqh.org/sites/default/files/core/Prior-Authorization-Referrals-278-Data-Content-Rule.pdf?token=oWySX4-N

Recommendations:

- *Withdraw the proposal to require full implementation of the PARDD by January 1, 2026, and instead finalize a staggered approach by communication type that adds functionality to the PARDD over time.*
- *Name not only the base standards but also the specific IG versions as a floor and create a SVAP*
- *Ensure IGs are created and approved as part of a fair and transparent process that is ANSI accredited and does not require a fee to comment or participate.*
- *Adopt new versions consistent with an SVAP process to be defined in regulations, and only after sufficient time for testing, implementation, evaluation, refinement, and public input.*

Build the Necessary Infrastructure

As outlined above in our comments on the Provider Access API, several infrastructure and foundational requirements and challenges must be resolved to ensure a successful implementation of the PARDD API. The PARDD API will also require established and known API endpoint connections between payers, providers, and vendors. The FAST initiative, which includes many AHIP members, is actively working to identify common scalability approaches to speed adoption and avoid each stakeholder reinventing the wheel. **CMS should advance the HL7® FHIR at Scale Taskforce (FAST) initiatives to address the ongoing challenges of patient matching and identity management, security and authentication, and access to the necessary digital endpoints.**

Recommendations:

- *Work with ONC to encourage adoption of the HL7 FAST solutions for, at minimum, identity resolution, security, and directory so that the requirements can be adopted at scale.*
- *Encourage HL7 to integrate UDAP into its IGs.*
- *Name not only the base standards, but also the specific IGs as provisional standards that serve as a floor to achieve further consistency across the industry.*
- *Clarify 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).*

X12 275/278 Standards

The publication of the Administrative Simplification proposed rule poses a challenge for the implementation of this rule if both are finalized. The industry was steadily working toward FHIR-based content and exchange standards for ePA in hopes for an end-to-end FHIR-based transaction in the future. Moreover, in this rule CMS would require the use of FHIR standards for the prior authorization exchange. However, the Administrative Simplification proposed rule, would not only maintain the X12 278 transaction but it would roll it forward to a new version and adopt the X12 275 for the associated prior authorization attachment. This essentially sends the industry in two different directions: providers and commercial plans toward X12-based

solutions, and plans in federal programs toward maintaining FHIR-based transaction converted to X12 standards. We do not believe the inclusion of a quality measure in MIPS as proposed would be sufficient incentive for providers to overcome the costs of converting the transaction, especially since commercial payers will only be required to support X12. Therefore, we expect that both commercial payers and providers would generally use the X12 standards. The point of administrative simplification is lost if two standards are required for overlapping use cases for plans in federal programs. This would not only increase resources required to implement the transaction but also could create confusion and delays in implementation as well as in processing while determining which organizations are using which standards for which transaction.

The current PAS IG requires the X12 278 to be transmitted as part of the PAS FHIR bundle, but this is because the regulation currently requires the X12 278 to be used somewhere in the transmission. Converting from FHIR to X12 is unnecessary and inefficient. Finalizing the X12 275 would magnify this inefficiency. Moreover, the FHIR-based exchange includes additional functionality in the CRD and DTR IGs than is included in the X12 transaction. Under 45 CFR 162.940, the Department provides for exceptions from the HIPAA standards to permit the testing of proposed modifications. The HL7 Da Vinci Project received an exception to test a fully FHIR-based transaction, which is underway to collect data, lesson learned, and determine a return on investment (ROI). However, this process is extensive requiring application, data collection, an evaluation report etc. The exception process in not laid out in statute and could be modified. Given the widespread use cases being built in FHIR, we do not believe this existing process will serve the industry or the government well going forward.

Recommendations:

- *Work with the broader Department to remove the prior authorization redundancy from the Administrative Simplification rule.*
- *Work with the Department to improve the HIPAA exceptions process such that it is less onerous and more flexible to facilitate innovation.*
- *Collaborate with HL7 to expand the existing FHIR pilot exception and encourage greater participation.*
- *Alternatively, the Department could create and participate in its own pilot project to test FHIR among willing trading partners starting with the FHIR end-to-end solution for prior authorization to speed maturity and adoption.*
- *Ensure the required prior authorization transaction is either solely FHIR-based once the IGs are mature, the ROI demonstrated, and it is tested at scale, or at minimum the X12 278 standard is retained, rolled to the version 8020, and the X12 275 standard is not adopted for the purpose of prior authorization.*

<u>Alternative Phased-In Approach</u>

CMS requests comments on an alternative phased-in approach to implementing the PARDD API. CMS notes it would have proposed that impacted payers make available 25 percent of their prior authorization rules and documentation requirements available by January 1, 2026, at least 50 percent available by January 1, 2027, and 100 percent available by January 1, 2028, but did not, given the potential for provider burden due to variability in rules. Availability would have been prioritized by the highest number of requested items and services.

Rather than phasing-in the full process for a certain percentage of items and services, we suggest that CMS stagger the functionalities available through the PARDD API, as noted before. For example, CMS could start with implementation of the HL7 Coverage Requirements Discovery (CRD) IG to allow providers to determine if a prior authorization is required. Next, CMS could implement the Da Vinci Documentation Templates and Rules (DTR) IG to allow providers to retrieve the required documentation. Finally, CMS could implement the Da Vinci Prior Authorization Support (PAS) FHIR IG to allow direct submission of the prior authorization request from the EHR. By staggering implementation in this manner, CMS could allow the infrastructure to mature and provide payers, providers, and EHR vendors time to build their capabilities and avoid frustrating providers by unnecessary variation in when a prior authorization request can be submitted electronically.

Recommendations:

- Withdraw the proposal to require full implementation of the PARDD by January 1, 2026, and instead finalize a staggered approach by communication type that adds functionality to the PARDD over time.

Implement Concurrent Requirements on Vendors

AHIP recognizes that advancing ePA will require participation and investment from all stakeholders, including health information technology developers. However, the integration of ePA technology into EHRs could reduce the burden on providers and increase the likelihood of adoption. Moreover, by incorporating the ability to retrieve critical information at the point of care via EHRs or other interfaces, ePA solutions can facilitate transparency of information and decision making, resolving another key reported burden of the prior authorization process. **CMS should work with ONC to establish specific requirements for EHR developers to include these Prior Authorization API functionality and capabilities in their technologies as part of the Certified Electronic Health Record Technology (CEHRT) program.**

Recommendations:

- *Work with ONC to establish requirements for EHR developers to build connections to the PARDD and Provider Access APIs as part of the CEHRT program.*

II. D. 4. Requirement for Payers To Provide Status of Prior Authorization and Reason for Denial of Prior Authorizations

II. D. 4. A. Reason for Denial of Prior Authorization

CMS proposes to require impacted payers to include a specific reason when they deny a prior authorization request, excluding prior authorization decisions for drugs, regardless of the method used to send the prior authorization decision.

As we noted above, there is not a single national, comprehensive national standard that applies across all prior authorization modalities, payers, and technologies. X12 and CAQH developed reason codes and operating rules, respectively. CMS established codes that are primarily used in FFS Medicare, while many private payers established their own proprietary codes to communicate this information. As such, it is not clear how the industry would reconcile the

existing codes and potentially add new one for this purpose. CMS proposes in the rule that for denials sent using the X12 278 standard, payers must use the codes from the designated X12 code list. However, for responses sent through portals, via fax, or other means, payers may use proprietary codes or text to provide denial reasons. This variation in coding by modality will make it challenging to convert these codes to a FHIR resource at this time.

Currently, CMS requires that beneficiaries and providers receive communications on decisions made for prior authorizations, including denial rationale, but the communication is in writing. We ask CMS to clarify that electronic communication could replace the current requirements for a written response.

Recommendations:

- *Clarify the difference between the policies in this proposed rule and the interaction with the written notice currently required.*
- *Engage a standards development organization to establish a taxonomy standard to promote consistency in electronic communications of the reason for a prior authorization denial.*

II. D. 5. B. Proposals To Address Timeframes for Decisions on Standard and Expedited Prior Authorization Requests

CMS proposes to require impacted payers (not including QHP issuers on the FFEs) to send prior authorization decisions within 72 hours for expedited (i.e., urgent) requests and seven calendar days for standard (i.e., non-urgent) requests. CMS also proposes extensions up to 14 calendar days under limited circumstances.

CMS seeks comment on what solutions would need to be addressed, for and by payers, to comply with the proposed timeframes for handling prior authorization review and approval activities. CMS also seeks comment on what changes payers or providers would need to make in their workflows or systems to reduce decision timeframes from 14 days to 7 calendar days (for standard prior authorization requests) and from 72 hours to 1 day or 24 hours (for expedited prior authorization requests).

Without a critical mass of providers positioned to link to the PARDD API, achieving shorter prior authorization turnaround timeframes will be challenging. At minimum, the request should be electronic. **The proposed turnaround timeframes should only apply in instances where the provider uses ePA (either through the API or using the X12 278/275) to make a prior authorization request.** Shorter timeframes for responses should not apply in instances where prior authorization requests are being made by phone, fax, or other manual processes. This will provide an added incentive for greater adoption of electronic prior authorization requests, particularly for those provider specialties that have been slower to adopt EHRs with ePA functionality.

We do agree with CMS that extensions can be justifiable such as when an enrollee requests the extension, there is a need for additional medical evidence from a non-contract provider that may change the payer's decision to deny, or when it in the enrollee's best interest due to extraordinary, exigent, or other non-routine circumstances, such as a natural disaster. Aligning

with the MA extension reasons as well as the 14-day extension timelines for both standard and expedited requests would create consistency.[25,26]

Recommendations:

- *Tie the shortened prior authorization turnaround timeframes to the availability of the PARDD APIs and/or the X12 275/278.*
- *Finalize the proposal the proposal to allow extensions of up to 14 days under limited circumstances that are currently available to MA plans.*
- *Apply the shortened timeframes only to ePA requests made by a provider.*
- *Clarify that the shortened timeframes apply to initial prior authorization decisions and that existing timeframes applicable to the appeals process would still apply.*
- *Clarify that the timeframes are tied to the impacted payer's receipt of the required documentation necessary to support the provider's prior authorization request.*

II. D. 6. Requirements for Timing of Notifications Related to Prior Authorization Decisions

II. D. 6. A. MA Organizations

CMS proposes to require MA organizations to notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after the organization receives the request for a standard pre-service organization determination for a medical item or service.

AHIP appreciates the importance of providing members with timeline notifications on the determinations of prior authorization requests. However, as noted above, without a critical mass of providers adopting ePA, achieving timeframes to make prior authorization determinations and notify patients will be challenging. **The proposed turnaround timeframes should only apply in instances where the provider uses ePA (either through the API or using the X12 278/275) to make a prior authorization request.** Shorter timeframes for notifications should not apply in instances where prior authorization requests are being made by fax, phone or other manual processes. CMS should also change the requirement from seven calendar days to seven business days to allow plans to respond in a way that is both timely and accurate.

CMS should coordinate with states to resolve conflicts between this proposed rule and existing state laws and regulations. We urge CMS to defer to state law where applicable.

Recommendations:

- *Apply the shortened notification timeframes only to ePA requests made by a provider.*
- *Revise the proposal from seven calendar days to seven business days.*
- *Defer to state laws and regulations where applicable.*

[25] 422.568 & 422.572
[26] https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf Page 42.

II. D. 6. B. Medicaid Fee-for-Service, Including Beneficiary Notice and Fair Hearings

CMS proposes to specify regulatory timeframes to provide notice of decisions on both expedited and standard prior authorization requests beginning January 1, 2026.

II. D. 6. C. Medicaid Managed Care

CMS proposes that, beginning with the rating period that starts on or after January 1, 2026, Medicaid managed care plans must provide notice of standard authorization decisions within state established timeframes that may not exceed 7 calendar days following the plan's receipt of the request for service.

AHIP appreciates the importance of providing members with timeline notifications on the determinations of prior authorization requests. However, as noted above, without a critical mass of providers adopting ePA, achieving timeframes to make prior authorization determinations and notify patients will be challenging. **The proposed turnaround timeframes should only apply in instances where the provider uses ePA (either through the API or using the X12 278/275) to make a prior authorization request.** Shorter timeframes for notifications should not apply in instances where prior authorization requests are being made by fax, phone or other manual processes.

CMS should coordinate with states to resolve conflicts between this proposed rule and existing State laws and regulations. We urge CMS to defer to state law where applicable.

Recommendations:

- *Apply the shortened notification timeframes only to ePA requests made by a provider.*
- *Defer to State laws and regulations where applicable.*

II. D. 6. D. CHIP Fee-for-Service and Managed Care

CMS proposes that, beginning on January 1, 2026, decisions related to prior authorization of health services would be required to be completed in accordance with the medical needs of the patient, but no later than 7 calendar days after receiving the request for a standard determination and 72 hours after receiving the request for an expedited determination, unless an alternative option is preferred by industry based on public comments.

AHIP appreciates the importance of providing members with timeline notifications on the determinations of prior authorization requests. However, as noted above, without a critical mass of providers adopting ePA, achieving timeframes to make prior authorization determinations and notify patients will be challenging. **The proposed turnaround timeframes should only apply in instances where the provider uses ePA (either through the API or using the X12 278/275) to make a prior authorization request.** Shorter timeframes for notifications should not apply in instances where prior authorization requests are being made by fax, phone or other manual processes.

CMS should coordinate with States to resolve conflicts between this proposed rule and existing State laws and regulations. We urge CMS to defer to state law where applicable.

Recommendations:

- *Apply the shortened notification timeframes only to ePA requests made by a provider.*
- *Defer to State laws and regulations where applicable.*

II. D. 7. Extensions, Exemptions, and Exceptions

II. D. 7. A. Extensions and Exemptions for Medicaid and CHIP FFS Programs

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

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

CMS should coordinate with states to resolve conflicts between this proposed rule and existing state laws and regulations. We urge CMS to grant exemptions to states that have already implemented ePA solutions that differ from CMS' policy. For example, Ohio has recently implemented a centralized portal for all Medicaid prior authorization requests.[27] These exemptions should apply to both to FFS programs and MCOs operating in States that have already implemented an ePA solution.

Recommendation:

- *Finalize the proposal to allow extensions and exemptions for Medicaid and CHIP FFS programs for the PARDD API.*
- *Clarify that a state can request a second extension, if circumstances warrant, in the following year rather than seeking an initial exemption.*
- *Work with states to resolve conflicts between current state policies and the proposed rule and grant exemptions to FFS programs and MCOs operating in States that have already implemented ePA solutions.*
- *Establish an exceptions and exemptions process across all APIs for all impacted payers.*

II. D. 7. B. 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 implementation would pose significant barriers.

We agree with CMS that an exception process is warranted to ensure that implementation of the API by QHPs, and that this would not result in consumers having few or no plan options in

[27] https://medicaid.ohio.gov/resources-for-providers/billing/prior-authorization-requirements/prior-authorization-requirements

certain areas. We also support consistency of this policy with the policy previously provided under the Patient Access API in the Interoperability final rule. However, as noted above, we believe impacted payers of all types may have difficulty implementing these extensive requirements.

Furthermore, CMS should coordinate with States to resolve conflicts between this proposed rule and existing State laws and regulations. We urge CMS to grant exemptions to states that have implemented state-level policies that may conflict with CMS' proposed policy. For example, Arizona has recently enacted legislation and published subsequent guidance establishing the use of uniform prior authorization request forms. We are concerned that layering multiple conflicting policies will create confusion and operational process challenges for QHP issuers and providers. We ask CMS to work with states to resolve these differences and ensure clarity to issuers on any exemptions from state or federal requirements.

Recommendations:

- *Finalize the proposal to allow exceptions for certain QHP issuers to the PARDD API.*
- *Grant exemptions to payers in states that have implemented state-level policies that conflict with the PARDD API.*
- *Establish both an exception and an exemption process across all APIs for all impacted payers.*

II. D. 8. Public Reporting of Prior Authorization Metrics

CMS proposes to require impacted payers to publicly report certain prior authorization metrics by posting them directly on the payer's website or via publicly accessible hyperlink(s) on an annual basis. This proposed reporting would be at the organizational level for MAOs, the state level for Medicaid and CHIP FFS, the plan level for Medicaid and CHIP managed care, and the issuer level for QHP issuers on the FFEs.

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 explain 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.

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.[28] 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.[29] Most recently, CMS has added new prior authorization requirements in Medicare FFS for certain outpatient services[30] as well expanded its non-emergent ambulance prior authorization demonstration program.[31] Additionally, Medicare FFS is in the process of implementing a prior authorization program for advanced diagnostic imaging that targets outlier physicians, thereby helping to protect patients from unnecessary exposure to potentially harmful radiation from inappropriate imaging.[32]

We are concerned that, as proposed, these metrics do not consider provider-side factors such as incomplete documentation or inappropriate requests. As such, they do not provide an accurate picture of payer quality.

Instead of requiring public reporting of these metrics, data could be confidentially reported to CMS as is currently done under existing programs. This approach would allow CMS to track outliers but avoids providing misleading information to consumers, as the proposed metrics do not show information about quality and safety or potential regional variation.

As noted elsewhere in this letter, an accredited standards development organization should develop standardized codes to document the reason a prior authorization was denied. Once fully tested, CMS could revise the metrics to include information on the reason for denial and allow a more fulsome picture of the potential value versus the burden of a plan's prior authorization processes.

CMS should also consider practical issues with implementing these metrics as proposed. For example, different utilization management vendors may count initial denials that were later

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[28] https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0181970
[29] https://www.gao.gov/assets/700/691381.pdf
[30] https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0 and https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-2
[31] https://www.cms.gov/newsroom/press-releases/cms-expand-successful-ambulance-program-integrity-payment-model-nationwide
[32] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/appropriate-use-criteria-program

approved after receiving the necessary clinical documentation differently. Some vendors may amend the initial request while others count the revised request as a new request. If CMS finalizes the metrics as proposed, we ask that the agency develop guidance for payers and vendors to promote consistent calculation and implementation of publicly reported metrics to allow for fair comparisons across payers and ensure accurate information for consumers.

Recommendations:

- *Remove the proposed requirement to publicly report the identified metrics, given the uncertain value of these metrics to consumers.*
- *If CMS finalizes its proposal, consider the following modifications:*
  1. *include information on the reasons for the prior authorization denials;*
  2. *report information to CMS (similarly to MCO reporting to states and the MA reporting requirements), rather than publicly;*
  3. *require reporting to CMS (or public reporting if impacted payer public reporting is finalized) by providers regarding their use of ePA technology; 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.*
  5. *provide implementation guidance to ensure consistent calculation of these metrics*

II. D. 9. ‘‘Gold-Carding’’ Programs for Prior Authorization

CMS seeks comment for consideration for future rulemaking on how to measure whether and how such gold-carding or prior authorization exemption programs could reduce provider and payer burden and improve services to patients. CMS also seeks comment on the incorporation of such a measure into star ratings for MAOs and QHPs.

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 areas identified in a Consensus Statement on Improving the Prior Authorization Process[33] that AHIP developed in collaboration with the American Hospital Association, American Medical Association, American Pharmacists Association, BlueCross BlueShield Association, and Medical Group Management Association.

However, any future gold programs should be voluntary as there is no single solution that will work for all payers and providers. Moreover, gold carding focuses on exempting some providers from the prior authorization process, rather than improving processes for all parties: providers, payers, and patients. We believe that CMS should continue to focus on facilitating a transition to

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

electronic prior authorization and exploring ways to leverage technology to maintain the important safety checks that prior authorization provides while reducing burden on providers.

AHIP recently conducted an Industry Survey on Prior Authorization and Gold Carding.[34] Our research found that use of gold carding has increased from 2019-2022 and that gold carding programs work best for items and services where there are clear and consistent clinical standards of care and for providers with sufficient prior authorization volume and high approval rates. Our research also found potential risks to gold carding such as a reduced quality of care or increased costs without any improvement in quality. Survey respondents indicated that frequent reviews of provider performance are vital, given the potential for performance to slip once a provider has been gold carded.

Overall, our survey found mixed reviews and results of gold carding programs, reinforcing the importance of voluntary and customizable programs. While gold carding programs offer opportunities to improve efficiencies, there are multiple challenges to their wholescale adoption, such as the need for well-defined inclusion criteria, selective and targeted application, and regular performance review.

Because of these challenges, we do not support CMS developing a future measure for the star ratings programs for MAOs or QHPs. Such a measure would compare plans directly to each other without considering factors such as state laws, regional variation, or provider practice patterns. If CMS does pursue development of such a measure it must include appropriate risk adjustment to account for factors outside of a plan's control and include minimum required sample size to protect against very small sample sizes that are not statistically significant or when data that is not reflective of the process.

Recommendations:

- *Maintain current flexibilities that permit payers to customize gold carding programs based on the specific needs and characteristics of their provider partners and the consumers they serve.*
- *Forgo pursuing development of a gold carding measure for the star ratings programs for MAOs or QHPs.*
- *Do not require payers to include gold carding in their prior authorization policies.*

II. E. Electronic Prior Authorization for the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and the Medicare Promoting Interoperability Program

II. E. 2. Electronic Prior Authorization

CMS proposes a new electronic prior authorization measure for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS, as well as for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program. To meet the measure, a prior authorization must be requested electronically from a PARDD API

[34] https://www.ahip.org/resources/new-survey-effective-gold-carding-programs-are-based-on-evidence-and-value-for-patients

using data from CEHRT. Under this proposal, MIPS eligible clinicians, eligible hospitals, and CAHs would be required to report the number of prior authorizations for medical items and services (excluding drugs) that are requested electronically from a PARDD API using data from CEHRT.

We agree that moving toward industry-wide adoption of ePA transactions based on existing national standards has the potential to streamline and improve the process for all stakeholders. However, successful implementation of ePA will require collaboration and coordination across many stakeholders in a complex ecosystem. One-sided requirements that require impacted payers to build Application Programming Interfaces (APIs) will not result in the broad adoption necessary to achieve the benefits. While health insurance providers can build APIs to facilitate ePA, these tools will have minimal value if EHR vendors do not build the necessary connections to allow clinicians to access them as part of their workflow, and a substantial cohort of clinicians are not incentivized to adopt their use.

The Fast PATH study found numerous benefits of ePA for providers. First, the results showed that ePA resulted in fewer phone calls and faxes related to prior authorization. Among experienced users, a majority experienced less burden related to phone calls and faxes after implementation of ePA authorization. Our results showed that 54 percent reported fewer phone calls and 58 percent reported fewer faxes leading to respondents reporting 63 percent less time spent on the phone and 62 percent less time spent on faxes. Fast PATH also found that 60 percent of respondents found that ePA made it easier to understand if prior authorization was required, 57 percent found it was easier to understand prior authorization requirements, and 54 percent found it was easier to view prior authorization decisions.

A significant finding of Fast PATH was that experienced users benefited the most from implementing ePA. The results clearly showed that the more frequently a provider used the technology solution, the bigger the benefit the provider experienced in ease of understanding prior authorization information and reduced burden.

To realize the greatest benefit from ePA, stakeholders should explore available pathways to increase the use of such technology. These pathways could include a combination of: (1) increasing the availability of the technology to providers; and (2) increasing the use of the technology where it is already available by identifying and addressing challenges, such as provider readiness and training, workflow integration, and incentives for providers to use the technology.

CMS and ONC should outline a roadmap for ePA that leverages the CEHRT program, Information Blocking final rule, and Interoperability final rule and outlines consistent requirements on all stakeholders. If health insurance providers are required to build APIs to support ePA, HIT developers should be required to build connections to those APIs and providers should be required to use them.

We appreciate CMS proposing these measures as a first step to promoting adoption of the PARDD. **We urge CMS to adopt these measures for MIPS and the Medicare Promoting Interoperability Program as first steps to incentivizing adoption of ePA.** CMS should also explore ways to use these measures in its other quality reporting and value-based purchasing programs, such as the Medicare Shared Savings Program (MSSP) to promote adoption of ePA broadly across the health care system. Once payers have implemented the PARDD API and

vendors have built the necessary connections outlined below, CMS should first have a period of reporting and then include these measures in providers' scores in MIPS and the Promoting Interoperability program to further incentivize adoption of ePA.

Finally, CMS should work with stakeholders to consider best data options for public reporting related to these measures on the *Care Compare* website. Sharing this data could help consumers choose providers who could better facilitate their care by adopting ePA and allow payers to understand providers' willingness to implement standards-based ePA and explore solutions to increase adoption. Appropriately designed public reporting may also incentivize provider adoption of ePA.

Recommendations:

- *Finalize the proposal to add and require the ePA measure for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS, as well as for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program*

Implement Concurrent Requirements on Vendors

To advance adoption of ePA by providers, health information technology developers will need to play a leading role. Integration of ePA technology into EHRs could reduce the burden on providers and increase the likelihood of adoption. Moreover, by incorporating the ability to retrieve critical information at the point of care via EHRs or other interfaces, ePA solutions can facilitate transparency of information and decision making, resolving another key reported burden of the prior authorization process.

Recommendations:

- *Work with ONC to establish specific requirements for EHR developers to build connections to the payer PARDD and Provider Access APIs into their technologies as part of the CEHRT program.*

II. F. INTEROPERABILITY STANDARDS FOR APIS

II. F. 1. Modifications to Required Standards for APIs

In the Interoperability final rule, CMS included a requirement to implement, maintain, and use API technology that meets the following implementation specifications codified at 45 CFR §170.215:

- ***Standard.*** HL7® Fast Healthcare Interoperability Resources (FHIR ®) Release 4.0.1
- ***Implementation specification.*** HL7 FHIR® US Core Implementation Guide STU 3.1.1
- ***Implementation specification.*** HL7 SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the "SMART Core Capabilities"
- ***Implementation specification.*** FHIR Bulk Data Access (Flat FHIR) (v1.0.0: STU 1), including mandatory support for the "group-export" "OperationDefinition"
- ***Standard.*** OpenID Connect Core 1.0, incorporating errata set 1

CMS now proposes modifications to be more specific regarding the requirements for specific APIs. CMS also proposes specific language regarding the requirements applicable for each API in this proposed rule.

We appreciate CMS's efforts to clarify the requirements and agree with the proposal to add more specific language regarding which standards are applicable to each API.

Recommendations:

- *Finalize the proposal to update the requirements to be more specific about which standards, versions, and IGs apply to each API.*

Use of Updated Standards

In the Interoperability final rule, CMS established that an updated version of a codified standard could be used if the updated version does not disrupt an end user's ability to use a required API to access the data required for that API.[35] CMS proposes to extend this same policy to the Provider Access API, P2P API, and PARDD API.

AHIP supports naming standards to promote consistent data exchange. We also recommend that a specific version be named as a floor and that a formal standards version advancement process (SVAP) be developed similar to the ONC process. This will give the industry and HL7 the opportunity to continue refining, testing, and deploying new versions yet ensuring the industry implements these policies in a consistent manner.

Recommendations:

- *Develop and implement a standards version advancement process (SVAP) that will allow the industry to advance harmonically to newer versions of the specific IGs without having to wait for new federal regulations.*
- *Adopt new versions only after sufficient time for public-private input, testing, implementation, evaluation, and refinement.*

II. F.2. Recommended Standards To Support APIs

CMS proposes to require that impacted payers use API technology conformant with the standards at 45 CFR §170.215 that it proposes as applicable for each set of API requirements. CMS states it is not ready to propose specific IGs as a requirement. Therefore, while CMS strongly recommends payers use certain IGs for the Patient Access, Provider Access, P2P, and PARDD APIs, the agency is not proposing to require their use.

As noted above, AHIP supports naming not only the base standards but also the specific implementation guides (IGs). We further recommend that a specific version of both base standards and IGs be named as a floor and that a formal standards version advancement process be developed similar to the ONC process. This will give the industry and HL7 the opportunity to continue refining, testing, and deploying new versions yet ensuring the industry implements these policies in a consistent manner.

[35] 85 FR 25532

We are concerned without a requirement to use specific IGs we will not achieve the level of interoperability necessary to support this data exchange. However, given the standards and IGs are an extension of federal policy that does not go through the rulemaking process, it is critical that the development process be fair, transparent, and open to all stakeholders and that policy decisions are not delegated to this process, but are made through formal agency mechanisms. For example, the IG creation process is currently driven by a limited number of volunteers that do not broadly represent the industry creating Resource/Profile versioning issues. Ensuring there is no fee to fully participate in the process for the regulatorily required exchanges and relying on an ANSI accredited process to develop the IGs would improve the approach.

Recommendations:

- *Name not only the base standards but also the specific IG versions as a floor and create a SVAP.*
- *Ensure IGs are created and approved as part of a fair and transparent process that is ANSI accredited and does not require a fee to comment or participate.*
- *Adopt new versions consistent with an SVAP process to be defined in regulations, and only after sufficient time for testing, implementation, evaluation, refinement, and public input.*

III. REQUESTS FOR INFORMATION

III. A. Request for Information: Accelerating the Adoption of Standards Related to Social Risk Factor Data

CMS reissues a request for information included in the December 2020 rule on barriers to adopting standards and opportunities to accelerate adoption of standards, related to social risk data. CMS seeks comments on how to better standardize and share this data.

AHIP strongly agrees with the importance of having standardized data on social risks to better inform care, remove barriers to care and healthy living, reduce disparities, and advance health equity. We also recognize that standardization of social risk data can make it easier for CMS and the industry to aggregate and analyze the data and make "apples to apples" comparisons across organizations and programs.

<u>Standardized Coding</u>

For years, many states, health providers, and health plans have already invested resources to collect standardized data on their members' social needs, drawing on social determinant of health screening tools and toolkits such as PRAPARE,[36] Accountable Health Communities,[37] WellRx,[38] We Care,[39] or others. These tools focus on similar social risk domains but the questions may differ slightly. An organization may use one of these tools in its entirety or select certain questions from one tool and other questions from another tool. Thus, requiring organizations to devote resources to modifying their data collection and IT systems to standardize around specific

[36] https://prapare.org/the-prapare-screening-tool/
[37] https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf
[38] https://www.jabfm.org/content/29/3/414
[39] https://www.bmc.org/pediatrics-primary-care/we-care/we-care-model

questions could disrupt the continuity of existing assessments and jeopardize linkages to historical data and related analytics. Instead, **we urge CMS to standardize around the social need using specific interoperable codes that could be reported for analysis and comparison.**

To accomplish this, CMS could look to the Gravity Project[40] for standardized value sets, interoperable codes, and HL7 technical standards to document standardized data on social needs. Interoperable codes could include ICD-10 Z codes, LOINC codes, SNOMED codes, among others. By focusing on standardizing the *need* rather than the *question*, social risk screening could more easily be scaled by utilizing existing systems and infrastructure and allow organizations to focus on needs and person-centered approaches that best meet the needs of their members while still promoting standardization and interoperability for data analysis and comparisons. For additional safeguards, CMS could specify which social risk screening tools are permissible to ensure organizations use questions from validated and vetted tools that have been tested by different communities to ensure they are person-centered and sensitive.

To ensure successful social risk data exchange, work is still needed to fill in gaps in coding around social risks, whether building out or refining structured data on social risks (e.g., ICD-10 Z codes, LOINC codes, SNOMED codes) or building out codes to document the services that are provided to mitigate social risks (e.g., HCPCS codes and CPT codes). Standardized values are also needed to understand to what degree or magnitude there is a social risk need so that it can be addressed and interpreted similarly by all entities.

If CMS would like to place additional safeguards to ensure that only validated, vetted, and community appropriate SDOH screening tools could be used, CMS could specify which SDOH screening tools are permissible. CMS could look to the Gravity ProjectGravity Project[41] or to NCQA's list of permissible to SDOH screening tools to meet their SDOH Screening and Intervention HEDIS measure for lists of recommended SDOH screening tools. This will ensure that only patient-centered questions from validated and vetted tools that have been tested by different communities for sensitivity will be used.

Alignment of Data Standards and Measures of Social Risks

A major challenge to equity efforts is that health plans, hospitals, and clinicians are following various federal, state, and accreditation data collection requirements and measures on social risks. Data collection standards that vary hinder efforts to aggregate, analyze, and enable apples-to-apples comparisons across markets and across health care entities. For example, providers are often asked or required to use ICD-10 Z codes to document social risks, but health plans are required to use LOINC codes to document social risks to meet NCQA's new HEDIS measure on social risk screening and intervention. These varied coding requirements will lead to duplicative social risk screening and hinder data sharing and collaboration across the health care ecosystem. Having consistent, interoperable social risk data would allow the health care ecosystem to collect this data when most appropriate and convenient for the patient and share the information with other partners with patient consent to inform patient care and population health management efforts as well as to address disparities in access to care and outcomes more effectively. **We**

[40] https://thegravityproject.net/
[41] https://thegravityproject.net/

recommend CMS support alignment of social risk data standards for use in quality measures at an ecosystem level through federal policy changes to advance health equity.

Incentives for Coding

Use of standardized codes by providers continues to lag. Many providers are still not aware of the availability and value of codes (such as Z codes, LOINC codes, or SNOMED codes) to document health-related social needs. Many EHR systems do not have easy pathways to add these codes to the problem or diagnostic list or on the back-end. Providers also have concerns with adding Z codes to the problem or diagnostic list because they feel individually responsible for addressing health-related social needs that occur outside of the clinician's office. Moreover, there may be a need to revise the language associated with these codes ensuring that it is neutral to ensure consumers feel comfortable responding and clinicians feel comfortable asking the necessary questions. This challenge is heightened by the recent enforcement of the Interoperability and Patient Access Final Rule and Cures Act Final Rule. These rules require health plans and providers to make information available to consumers through standards-based application programming interfaces (APIs). As such, clinicians may be hesitant to add a code that the patient may not understand or agree with if there is a chance that code could be seen by the patient when they access their records through these APIs. **CMS should consider developing and implementing incentive programs to increase provider adoption rates of standardized social risk codes and tools, such as a MIPS practice improvement activity on social risk screening using ICD-10 Z codes. CMS should also work with ONC to ensure EHRs can capture all available interoperable codes, including Z codes, LOINC codes, and SNOMED codes.**

Protect Patient Privacy

We recommend that safeguards to protect patient privacy be implemented across the entire process of social risk data collection, reporting, and data sharing. We recommend that CMS include guidance for best practices on data collection as well to ensure that individuals retain agency in providing sensitive information on social risk or can choose to decline to provide this information. This holistic view of data handling would strengthen consumer ownership and agency while ensuring sensitive data are accurate and protected. We also ask that stakeholders be prepared to address the sanctity of personal data to avoid the risk of discrimination. For example, organizations should have appropriate policies for privacy, data sharing, data governance, and data breach in line with the HIPAA and the HITECH Act requirements.

While we appreciate the need for better data to address social risk and to share it through interoperable standards, we must reiterate our comments above that data sent to third-party apps may no longer be covered by HIPAA. As CMS institutes requirements to screen for social risk factors and ONC includes additional information on SDOH as well as individually identifying information the risk to a person's privacy continues to increase. Organizations that are not regulated by HIPAA or HITECH should be governed by these requirements or brought under a similar regulatory framework (e.g., the FTC regulating entities with "HIPAA-like" requirements). While social risk data has an important role to play in helping inform care and ensure, promote population health management, and assess quality there must be appropriate protection and security of sensitive data. Moreover, **CMS must take the lead on educating**

consumers of the risks of sharing data via third-party apps and that they can opt-out of both providing information on their social risk and sharing data.

CMS should work with health plans and providers to emphasize the voluntary nature of these data collection efforts while encouraging data completeness. For example, it could be a mandatory field on an electronic form with a response choice that indicates the person chooses not to respond. It is important that individuals do not "have to" self-report data over and over with every health care entity. **We urge CMS to recognize as these policies evolve that not all patients wish to answer questions on their social risks.** Such refusals should be honored, and data collection entities should not be required to continuously ask individuals.

Include Social Risk Data Collection in the Numerator of Medical Loss Ratio

Health insurance provider investments in activities and interventions that offset social risks are neither considered "medical services" nor quality improvement activities for the purposes of calculating MLR. These activities that offset social risks (such as screening and interventions) should be included as a new category in the numerator of the MLR because these activities are medically related (not administrative) and they improve outcomes. **To improve the ability to collect interoperable social needs data, CMS should allow issuers to include such investments in the numerator of the MLR calculation.**

Bidirectional Data Sharing

Improving the flow of information across stakeholders would also improve the process of collecting social risk data. As noted above, data standardization and increased interoperability in information technology systems across the government, payers, regulators, and providers would help facilitate data flow. This would also help minimize the burden on consumers and the accuracy of data. Repeatedly being asked to provide sensitive information is abrasive, will likely create distrust, and will increase the likelihood of the collection of incorrect data. Moreover, conversations about social risk are sensitive and people will be most likely to share truthful information with a trusted party such as a health care provider with whom they have an established relationship. Operationalizing TEFCA would facilitate the process to share social risk data.

As noted in our comments on the Provider Access API, current data sharing requirements are one-directional. While plans are required to share data with providers, there are no requirements for providers to share with plans. Creating a bidirectional Provider-Payer Access API could allow the sharing of social risk data to support patients and address SDOH and minimize the number of times a person is asked for sensitive information. CMS should work with ONC to ensure the bidirectional flow of data based on the Information Blocking final rule provisions. Furthermore, CMS should consider the potential role of advances like TEFCA to support scaled exchange of large data sets on a more real-time basis in the future.

Finally, we must build up the necessary databases and exchange systems. As demonstrated by COVID-19, the public health information technology infrastructure is severely hamstrung by limitations of interoperability and data sharing between agencies, programs, and relevant stakeholders within and across each sector, including health insurance providers. Attempting to share new, complex data such as social risk will tax existing systems, including public health

agencies which have long been critical partners in the effort to address social barriers to care. There may be a role for organizations such as Health Information Exchanges (HIEs), Health Information Networks (HINs), or clinical registries to facilitate data exchange between public health and the clinical care delivery system. However, there is limited ability for these entities to exchange information electronically with each other. Using HIEs and HINs may also require organizations to pay a fee to each network. This creates duplication of data to ensure social risk data on individuals served is in each representative information system and also creates confusion as to which information system to use and when. Using APIs to share data would allow organizations to use existing information systems but share data in an interoperable manner and interoperability in a "collect once use many times" approach.

III. B. Electronic Exchange of Behavioral Health Information

CMS reissues an RFI on how to advance electronic data exchange among behavioral health providers. CMS seeks comments on how the agency might leverage APIs, or other solutions, to facilitate electronic data exchange with behavioral health providers who have lagged other provider types in EHR adoption.

AHIP appreciates CMS recognizing that behavioral health, small practices, and community organizations were not 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. Providers may also need education and support to shift their workflows to adopt technology.

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**.

Concerns about patient privacy and the interaction between HIPAA and the 42 CFR Part 2 rules may also lead to reluctance to share behavioral health data electronic. While regulations under 42 CFR Part 2 will be imminently aligning with HIPAA per the CARES Act, these regulations have yet to be made final. **CMS should work with providers to provide education on the changes to the 42 CFR Part 2 rules.** Additionally, provider education may be essential to convince behavioral health providers of the security of electronic data exchange. While electronic data exchange may be permitted, some providers remain reluctant to adopt it and believe paper or fax methods are more secure and less likely to compromise a person's privacy.

CMS' proposal for a new electronic prior authorization measure for MIPS eligible clinicians under the Promoting Interoperability performance category of MIPS, as well as for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability

Program, is an important first step to promoting adoption of the PARDD. **CMS should also explore ways to use these measures in its other quality reporting and value-based purchasing programs, such as the Medicare Shared Savings Program (MSSP), to promote adoption of ePA broadly across the health care system and among different types of providers.**

III. D. Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

CMS seek comments on evidence-based policies the agency could pursue that leverage health IT (HIT), data sharing, and interoperability to improve maternal health outcomes. CMS also seeks comments on leveraging the USCDI to address maternal health, as well as improving prior authorization policies that can negatively impact maternal health outcomes.

AHIP and our members are committed to improving maternal, newborn, and infant health outcomes for all Americans. Health insurance providers are committed to ensuring that our members receive high-quality care during pregnancy, childbirth and after delivery. In order to improve the birth outcomes of both mothers and their babies, maternity care must be safe, guided by sound medical evidence, and affordable. To support these goals, health insurance providers require hospitals in their networks to adhere to peer-reviewed medical guidelines for maternity care.

While we agree with the need to improve the prior authorization process through initiatives such as ePA, we do not believe that prior authorization policies negatively impact maternal health outcomes. **Prior authorization is an essential tool for health insurance providers to ensure members receive safe and effective care**. Prior authorization allows health insurance providers to promote timely, evidence-based, affordable, and efficient care. Prior authorization can reduce inappropriate care by preventing unsafe or low-value care and targeting where care may not be consistent with the latest clinical evidence. Unsafe, low-value, or care that is not evidence-based can contribute to potential harm to patients and unnecessary costs.

Moreover, prior authorization is not used frequently in maternal health care. AHIP members note that there is usually a generic inpatient stay authorization but not an authorization for a specific regimen of care. Ultrasounds may be the service that requires the most prior authorization. While the need for ultrasounds and what is authorized depends on the risk status of the pregnancy, there is a risk for overutilization and the use of the technology beyond what is supported by current clinical guidelines.

Payers are using approaches ranging from value-based care to advanced analytics to streamline the authorization process. Maternal care lends well to payment via episode or bundles which can reduce the need for prior authorization when compared to fee-for-service payment models. Payers have also implemented ePA to streamline requests and are exploring the use of advanced analytics and machine learning to reduce provider burden and improve response times.

However, there are a number of ways CMS could leverage HIT, data sharing, and interoperability to improve maternal health outcomes. First, **CMS could advance the bidirectional data sharing necessary to implement digital quality measures (dQMs) that could provide patients, providers, and payers with better information about the quality of**

maternal and infant care. CMS could create, and encourage measure developers to create, dQMs that leverage novel data sources or facilitate the collection of patient-reported data to understand the experience of new mothers and if their clinicians are adequately responding to their concerns. Standards for digital measurement of maternal and child health care will permit the integration of new data sources beyond claims such as directly from the medical record and patient-reported outcome measures, as well as significantly reduce the time and resources devoted to measurement.

We applaud CMS's creation of the Birthing Friendly Hospital Designation and implementation of the Maternal Morbidity Structural Measure in the Hospital Inpatient Quality Reporting Program (IQR). We encourage CMS to add additional quality measures addressing maternity care to the IQR program and to incorporate them into this designation. In order to assure that mothers are getting the recommended care at the recommended times, insurance providers rely on an array of quality measures, such as the rate of early elective deliveries, the rate of cesarean deliveries, and the rate of high-risk deliveries. Early elective deliveries can have serious consequences for the mother and baby. Births delivered via cesarean section result in surgeries that have the potential to create additional risk to the patient. Understanding that CMS aims to apply the Universal Foundation to as many programs as possible, including IQR, **CMS should consider including the PC-01 Elective Delivery, PC-02 Caesarian Birth, and Severe Obstetric Complications measures as supplemental required measures for hospitals participating in IQR and subsequently including them in the Birthing Friendly designation to help stakeholders and patients better understand a hospital's performance on these essential metrics.** CMS could also explore ways to leverage measurement to reduce the risks to maternal health associated with intimate partner violence[42]. Measurement could lead to improved screening and thus better data capture and efforts to coordinate care.

We encourage CMS to continue to focus on maternity care as part of the IQR program and to explore additional measures that could be added to the program measure set. The Core Quality Measures Collaborative (CQMC), convened by CMS and AHIP, brings together health insurance providers, clinicians, employers, consumers, and regional collaboratives to align measures for use in value-based care programs and includes obstetrics and gynecology consensus core measures that address key clinical concepts in maternal and fetal medicine. **CMS should look to the CQMC obstetrics and gynecology core measures set as a source for additional measures to improve the quality of maternity care and to advance maternal health equity.**

ONC could also explore the possibility of adding new data elements to the USCDI to improve data capture and flow to support maternal health. Some key areas to explore ways to better capture hemorrhage events during delivery and a measurement of blood loss rather than abstract capture for notes.

Information is key to identifying disparities and achieving equitable care. CMS should also explore ways to leverage HIT to address disparities in maternal and infant outcomes and promote health equity. HIT can provide better data on maternal disparities through more defined quality measures, improved demographic data, and enhanced information flow on a patient's social

[42] https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/intimate-partner-violence-and-abuse-of-elderly-and-vulnerable-adults-screening

needs and risks, which ultimately provide a better understanding of patient lived experience and health risk factors. Standardized and interoperable data collection and sharing of patient demographic factors and SDOH is necessary to better understand a person's needs. HIT could facilitate the data collection process and reduce the burden on patients by minimizing patient exposure to repeated sensitive questioning, especially during labor or shortly after the birth of a new baby, as data can be collected one time and used more frequently thereafter.

Bi-directional data flow to facilitate care coordination could also improve maternal and infant health outcomes. **As noted in our response to the proposals of the Provider Access API, we urge CMS and ONC to use the Interoperability and Information Sharing Rules to improve the flow of data across stakeholders.** By implementing requirements for providers to share clinical and demographic data with payers, payers will be better able to respond to the needs of new mothers and facilitate improved postpartum care.

CMS could also explore ways to increase the use of telehealth to increase access to maternal health care. Integrating telehealth and other technologies into perinatal and maternal health care can help bridge the gaps in access to obstetric care in rural and underserved communities, leading to better maternal outcomes. More rural and low-income hospitals are closing their maternity wards and eliminating labor and delivery care to control costs, further exacerbating current maternity care deserts. The American Hospital Association states that at least 89 obstetric units close in rural hospitals from 2015 to 2019[43] and the March of Dimes has found that approximately 2.2 million women of childbearing age live in maternity care deserts.[44] Studies have found that pregnant people in rural areas face a higher risk of pregnancy-related complications[45] and those living in maternity care deserts are three times as likely to die during pregnancy and in the year after.[46]

Telehealth and technology tools can help improve the perinatal experience, serving to better connect patients with their providers, more efficiently and proactively monitor potential pregnancy complications, and ultimately help promote healthier moms and healthier babies. Perinatal telehealth interventions can include using videoconferences to replace or supplement in-person visits, implementing at-home digital monitoring through phone apps and other devices, and enabling consultation with specialists remotely, including maternal fetal medicine doctors. In the postpartum period, telehealth and other tools can be used to enable earlier postpartum follow-up visits and to provide access to lactation consultants (tele-lactation).

III. E. Request for Information: Advancing the Trusted Exchange Framework and Common Agreement (TEFCA)

CMS seeks comments on how enabling exchange under TEFCA can support the proposals in this rule, as well as policies in the CMS Interoperability and Patient Access final rule. CMS also

[43] https://www.aha.org/system/files/media/file/2022/04/Infographic-rural-health-obstetrics-15ap22.pdf
[44] https://www.marchofdimes.org/maternity-care-deserts-report
[45] https://www.commonwealthfund.org/publications/2021/sep/restoring-access-maternity-care-rural-america
[46] Wallace M, Dyer L, Felker-Kantor E, Benno J, Vilda D, Harville E, Theall K. Maternity Care Deserts and Pregnancy-Associated Mortality in Louisiana. Womens Health Issues. 2021 Mar-Apr;31(2):122-129. doi: 10.1016/j.whi.2020.09.004. Epub 2020 Oct 14. PMID: 33069560; PMCID: PMC8005403.

seeks comment on the agency's approach to incentivizing or encouraging payers to enable exchange under TEFCA.

As noted in our comments on the P2P, we believe TEFCA holds promise to advance CMS's interoperability goals. However, the next year will show whether there is enough support and participation to move forward with more complete and interconnected systems and processes. While we applaud the advances ONC and the Recognized Coordinating Entity (RCE) have made to stand up TEFCA, there are still outstanding questions about how this network will come together. TEFCA has the potential to advance interoperability and improve data access for all stakeholders. Once implemented, TEFCA will lay out important rules of the road and allow the creation of a nationwide "network of networks."

TEFCA depends on widescale adoption to be successful. **AHIP and its member plans strongly believe that TEFCA participation must remain voluntary, and stakeholders must see clear value in participating**. To accomplish this, however, the supported expanded purposes and use cases must appeal to a broad range of entities including not only health care providers, but also health plans, public health agencies, consumers, clearing houses, and other integral entities. Moreover, the process for choosing and advancing new use cases must be transparent, inclusive, and address appropriate health care data exchange needs.

Our expectation was that the initial health care payment and operations use cases would be structured to offer value to health plans to entice participation. As noted earlier in this letter, we support TEFCA's six expanded exchange purposes, including treatment, individual access service, public health, benefit determination, payment (utilization review), and health care operations (quality assessment and improvement, business planning and development). However, at the moment, TEFCA's exchange purposes seems very limited for the type of exchanges health insurance providers perform every day.

Equally important, the proposed Standard Operating Procedures (SOP) for Payment Risk Adjustment and Risk Management Exchange Purposes, in all likelihood, will not show enough benefit given associated risks and resources required for widescale health plan adoption.

ONC and CMS should ensure the inclusion of use cases in TEFCA that will make participation attractive not only to health care providers but to payers as well. For example, to encourage adoption and ensure TEFCA realizes its potential, CMS and ONC should advance use cases that address unmet needs or could leverage technology to reduce burden. By meeting these needs, ONC and CMS could foster the desire by health insurance providers and other stakeholders to join TEFCA and facilitate nationwide data sharing. **Rather than prioritizing the Payment Risk Adjustment and Risk Management Exchange use, CMS and ONC should explore ways to leverage TEFCA to meet the objectives of the Interoperability and Information Sharing Rules.**

We offer the following as potential voluntary use cases that could hold value for health insurance providers. However, it is essential that CMS does not mandate participation in TEFCA under these potential uses. Health insurance providers have invested significant resources in meeting the requirements of the current interoperability requirements. While TEFCA holds promise as a pathway to promoting interoperability, it is unreasonable to mandate major modifications so

soon after the initial implementation of these requirements. Instead, we make these recommendations as options that ONC and CMS could implement to encourage health insurance providers, as well as all appropriate health care stakeholders, to participate in TEFCA.

Longitudinal Health Records

We believe that consumers should have easy access to health information that is personalized and actionable, that they should be able to seamlessly share this information with others. In addition, we believe that the health information shared at the request of the consumer should be safely protected. We agree that payers can play an important role in ensuring consumers have access to their health information. In addition to the plans in federal programs implementing the Patient Access APIs, the majority of health insurance providers have web-based tools to share a variety of health information directly with their enrollees. Health insurance providers are continuously enhancing these tools to better meet their members' needs. However, for that information, as well as user trust, to be protected as it is exchanged across the ecosystem, all actors – providers, payers and third parties – must be held to consistent privacy and security standards.

We believe CMS should shift its approach to ensure that any large-scale exchange of consumer data (e.g., full clinical and claims records) is consumer-mediated and results in easy and meaningful access to comprehensive data. Consumer data beyond that which is needed for care coordination among payers is, and should remain, a component of the Patient Access API rather than the payer-to-payer exchange.

Impacted payers have already made full-scale claims data available to consumers through the Patient Access APIs. Through this technology, a consumer can already access their data and share it with an app of their choosing. Plus, they can do the same with their clinical information based on the comparable ONC information blocking requirements provisions on health care actors, as defined in the regulation. These investments and capabilities should be built on, not superseded by TEFCA. In addition, large scale data exchange should be supported by a secure entity that can integrate claims and clinical data, along with other sources such as patient-reported outcomes, to create actionable information and easy-to-use information for consumers. A solution, such as patient-centered data aggregation, should be part of a longer-term roadmap developed in collaboration with the industry.

By leveraging TEFCA to help consumers build their health records, CMS could protect patient privacy and security while streamlining data flow for all stakeholders. Payers and providers could share data through TEFCA while consumers could leverage it to facilitate the process of connecting records from multiple entities. Moreover, the flow-down provisions of the Common Agreement could fill an important gap in privacy as many third-party apps are not covered by HIPAA.

Payer-to-Payer Data Exchange

Interoperability holds great promise in allowing health insurance providers to facilitate better care for members and to take a more active role in care coordination. The payer-to-payer exchange specifically provides the opportunity to diminish potential disruptions for consumers who are changing plans and to help ensure continuity of care. However, sharing large amounts of

unnecessary data can have the opposite effect, requiring the new health insurance provider to sift through (and store) large amounts of irrelevant information looking for the facts necessary to effectively deliver benefits and care. By focusing the payer-to-payer data exchange mandate on sharing information that will facilitate the consumer's transition from one impacted payer to the next, CMS could facilitate a successful implementation of this policy. **To support this, CMS should focus on a subset of key coverage, clinical, demographic, claims (excluding payment rates), and encounter data exchanged in a standardized form and format, which can be easily integrated into the new payer's systems.** To facilitate CMS's goal of enabling longitudinal records, CMS and DoD/VA should also be required to participate in the payer-to-payer data exchange so consumer can transfer their relevant coverage data across all payers they may use across their care journey.

As CMS considers how to finalize the policies for the P2P data exchange, TEFCA could also play an important role. CMS should work with ONC and the RCE to ensure that TEFCA includes a voluntary payer-to-payer exchange use case early in its developmental roadmap. CMS then could permit the option of payers meeting the requirements of the payer-to-payer data exchange through TEFCA. By sending data through qualified health information networks (QHINs), payers would not have to build out extensive point-to-point connections, making the payer-to-payer data exchange more efficient and reducing the burden of implementation. This could also alleviate some of the current technical challenges such as a lack of digital endpoints and accurate patient matching. Given that the RCE expects to onboard QHINs in the coming months, it may benefit all parties to delay the payer-to-payer exchange implementation deadline to enable payers to leverage TEFCA to meet these requirements.

Prior Authorization

Another opportunity for increased efficiency that can be realized through the use of TEFCA is executing Prior Authorization transactions with providers. We recognize this would require shifting from current standards (i.e., X12 278, 275 transactions) to FHIR-based solutions. AHIP has supported the migration to FHIR while being sensitive to the fact that some entities have not yet implemented transactions utilizing FHIR. Additionally, ONC and the RCE are still working on a roadmap to incorporate FHIR in its approach to TEFCA. TEFCA must implement facilitated FHIR capabilities quickly in order to be more consistent with current and proposed CMS regulatory requirements for other health plan implementations of FHIR-based APIs for information sharing. Additionally, we note that CMS would need to allow FHIR to be used for Prior Authorization (i.e., the only current standard permitted is the X12 standards) and such a change will take time as regulations would need to be developed, education performed, testing completed, and other processes.

The submission by providers to health plans and payers of supplemental clinical documentation in support of a health care claim is another potential area of value application of TEFCA for health plans and payers, although this would require the adoption of attachment standards, currently being considered in a recently released CMS proposed rule. We are hopeful that this will be a significant development that will yield higher value and greater efficiencies within the health care system.

Quality Measurement and Population Health Management

The ultimate goal of information sharing is to improve health and health care for consumers. TEFCA could enable plans and providers to seamlessly share information to support the provision of high-quality care by supporting population health management, improving care coordination, and enabling better quality measurement. The electronic, bidirectional sharing of clinical information is one of the most promising opportunities for using TEFCA from our perspective. Accessing data would be faster, easier, cheaper, and more comprehensive. **By facilitating the exchange of clinical data, TEFCA could allow health plans to better support providers in the provision of patient care.**

First, clinical information from providers could be combined with health plan claims data to create population health management dashboards with actionable information for providers to improve care and outcomes. This data would allow providers to understand if their patients are up –to date on necessary screenings and other preventative care and facilitate better chronic disease management. Health plans could also use this data to support their own case management efforts and better facilitate care coordination. Plans have a unique, longitudinal view of a person's care and with real-time, enhanced clinical data would be better equipped to assist their members during transitions between providers.

Second, **TEFCA could also facilitate the process of quality measurement**. Quality measurement is crucial to understanding historical performance; however, currently it is burdensome on all parties to collect, report, collate, and analyze the necessary data. Technology holds promise to reduce the burden of reporting quality data while enhancing the information on quality available to all stakeholders. Digital quality measures (dQMs) and the electronic exchange of information through formats such as APIs could reduce the time and resources required to extract data from patient charts or other forms such as the surveys used to generate patient-reported outcome measures. ONC has launched the USCDI plus initiative to identify the data elements necessary to report dQMs. AHIP and CMS have partnered to convene the Core Quality Measures Collaborative (CQMC) to identify the current measures that should be prioritized for transformation to dQMs. A quality measurement use case could build on these efforts to accelerate the transition to digital measurement by allowing effective, secure and efficient access to such clinical data for quality measurement and reporting from the "source" (i.e., the EHR).

Data at the Point of Care

As noted in our comments on the Provider Access API, this exchange could be leveraged in the future to enable the exchange of dynamic data to support patient care such as identified care gaps to providers and admit/discharge/transfer alerts to payers. **However, CMS should work with ONC to ensure the bidirectional flow of data based on the 21st Century Cures Act (Information Blocking) regulation provisions and potential regulatory updates**. The patient care use case would require up-to-date data that can be easily parsed on both the payer and provider sides to support clinician decision-making at the point of care. Advances like TEFCA could have a potential role to support scaled exchange of large data sets on a more real-time basis in the future.

Our members believe that a good place to start would be a use case that is relatively simple and straight forward. For example, health plans would greatly value Admit/Discharge/Transfer (ADT) alerts from providers. As part of the Interoperability and Patient Access rule as well as the Information Blocking rule, providers must make admission-discharge-transfer (ADT) alerts available to other providers. However, they are not required to share such information with payers. Knowing these key steps in a patient's inpatient care journey would enable health insurance providers to better assist in care coordination and follow-up, such as alerting providers of their patient's status. This is a known point when errors and communication breakdowns occur, and health insurance providers are uniquely positioned to intervene in these situations to ensure enrollees receive coordinated care across settings and over time. Real-time alerts would allow timely interventions that claims data do not support. Given the technological infrastructure is already built, this would be a marginal addition for CEHRT vendors to build and providers to adopt. **As an early use case, TEFCA could facilitate the exchange of this vital information as currently, payers and providers do not have accurate information about the necessary digital endpoints to share this data.**

V. 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 $1.6B. In Table 24, CMS estimates providers could save $15.3B by adopting the proposals of the proposed rule.

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 potential conflicts with the Attachment Standards proposed rule. Moreover, the 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 longer implementation timelines and to resolve the discrepancies caused by the policies proposed in the Attachment Standards proposed rule. Impacted payer and provider burden will increase when attempting to align FHIR and X12 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 with the X12 278 and allow the FHIR-based transactions to enable the freedom to achieve the desired efficiency and outcomes. And CMS and ONC should apply comparable to providers and CEHRT vendors. Otherwise, CMS's estimates of achieved economies will be significantly overstated.

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. Moreover, as CMS highlights in Table 27, the majority of costs will be borne by payers (both health insurance providers and the federal government), while the majority of savings will be enjoyed by providers.

Recommendations:

- *Reconsider the proposed timeline and consider reshaping this rule into a roadmap with milestones along the journey that signal a new requirement is ready for implementation.*
- *Update the impact analyses based on changes in the FHIR standards and the associated IGs that would be needed to implement these proposed changes.*