March 13, 2023

Submitted via www.regulations.gov

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program [CMS-0057-P]

Dear Administrator Brooks-LaSure:

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to provide feedback on the Advancing Interoperability and Improving Prior Authorization Processes proposed rule. ACHP continues to support the Administration's health care modernization and digital transformation initiatives. We support the overall direction of the proposed rule and agree with making the prior authorization process less burdensome for payers and providers and, in so doing, avoiding care delays for patients.

ACHP represents the nation's top-performing non-profit health plans improving affordability and outcomes in the health care system. ACHP member companies are provider-aligned health organizations that deliver high-quality coverage and care to tens of millions of Americans across 37 states and D.C. They lead the industry in practical, proven reforms around primary care delivery, value-based payment and data driven systems improvement.

ACHP and our member companies are invested in the digital transformation of health care and the inevitable benefit this will have for consumers. Modernizing the process of prior authorization will be part of that future. We appreciate the opportunity to provide feedback on these proposed provisions to ensure the thoughtful implementation of these policies and that there are not costly unintended consequences for all stakeholders. Without endpoint standardization or sufficient provider incentives, ACHP is concerned the APIs proposed in this regulation will not integrate to other systems, potentially leading to a patchwork implementation of this policy. This, along with privacy concerns regarding the Provider Access API, may not advance interoperability in the way this regulation intends. Our comments and suggestions on the proposed provisions are below.

Patient Access API

ACHP requests CMS provide clarification on three of the data components proposed to be added for Patient Access API exchange. We seek further clarification about the requirement to include information about "quantity of item/service used to date under authorization." This data element may not be captured or reported as CMS intends and examples, or guardrails, for this provision would be beneficial.

We note that this will be challenging to incorporate, and potentially misleading for beneficiaries, if there are claims lags or variance in defining either "quantity" or "use" (e.g., quantities of durable medical equipment (DME) or similar supplies provided in advance, which could be subject to different reporting methodologies by the vendor based on individual units or packaging versus reporting months of use for a medical device as the "quantity" based on it being billed as a monthly rental). Additionally, because many payer authorizations do not incorporate specific quantities or quantity-based limits they are generally not subject to any form of integrated quantity tracking/reporting. Payers will be required to establish new methodologies for reporting and storing this information within existing information systems.

ACHP seeks further clarification about the materials required for a payer to share any provider-generated materials used to support a prior authorization decision, potentially including progress notes and images. Without a clearer definition or size limit of files, health plans may face significant administrative burden to transfer this immense quantity of data. Guardrails defining what provider-related materials should be included in this requirement will alleviate administrative burden. ACHP also requests CMS expand upon its definition of "date or circumstance under which the prior authorization ends."

ACHP recognizes CMS's limited authority to address privacy concerns related to third-party applications and urges the Administration to find a cohesive solution that does not solely rely on consumer education to mitigate significant risk. ACHP does not agree that the benefits of patient access to information completely outweigh the privacy risks of transferring this data to unregulated apps. Although ACHP appreciates CMS outlining specifically what health plans should include in patient education materials, there is little more plans can do to prevent inadequate third-party privacy policies from negatively impacting patients.

ACHP requests that CMS refrain from finalizing the requirement plans report on the specific third-party apps with which they are asked to exchange data. This provision to provide information about third-party apps and usage is not feasible without investing substantial and burdensome human and financial resources. This requirement would open health plans up to tracking this information that may not even be utilized by enrollees more than once and would not improve access to patient data. While ACHP appreciates CMS rescinding the requirement for health plans to receive attestations of third-party app privacy policies, we again raise our concerns that these applications remain unregulated and have access to personal health information with limited guardrails on how that information should be protected.

<u>Provider Access API</u>

ACHP has several concerns and recommendations related to the requirement for plans to establish and maintain a Provider Access API.

1. **Lack of Endpoint Compatibility**

In the absence of a required industry standard for the Provider Access API, ACHP recommends that CMS identify a process for regulating standards that allows for standards to evolve and improve on a timely and regular basis. Until this occurs, payers will struggle to ensure their developed APIs can connect to different provider EHR systems and vendor platforms. The lack of endpoint standardization between provider and payer systems will likely create technical difficulties as health plans implement this API across their provider networks and operationalize end-to-end processes in variable ways. As the implementation guides are recommended, rather than required, it leaves the potential for organizations to use alternatives or make modifications that would affect their exchange capabilities.

Additionally, the lack of a named standard and implementation guide may disincentivize vendors from creating payer solutions to assist in this process. While ACHP understands the regulatory burden of adopting new HIPAA-compliant standards, ACHP suggests CMS consider alternatives to simply suggesting certain standards or implementation guides be used. Some of those alternatives may include adopting a regular cadence of updating standards, requiring a baseline standard that provides flexibility for using a more current version of that same standard but with some level of backwards compatibility, or implementing this policy as a Trusted Exchange Framework and Common Agreement (TEFCA) use case as opposed to a Provider Access API.

2. **In-Network Providers**

ACHP requests CMS clarify the definition of an "in-network" provider. Many plans are concerned about how these proposed policies may affect leased networks—groups of providers that have contracts with plans but their in- and out-of-network status varies depending on a plan's benefit package. These networks are often rented or leased from other payers that have established their own unique standards via provider contracts (over which the renter or lessee plan has no control). These networks are commonly, though not exclusively, employed to supplement the geography of a plan's available provider network, particularly for smaller local or regional plans that would not otherwise have access to negotiated pricing in other regions or states. Including these providers may cause additional difficulties in the implementation of this policy.

3. **Patient-Provider Attribution**

If CMS decides to finalize the Provider Access API, ACHP recommends that it utilize stakeholder feedback to establish minimum criteria as proof of an authentic patient-provider relationship and the requirement should not be extended to out-of-network providers. While ACHP appreciates CMS' flexibility in allowing plans to determine how to approach the attribution process, this process could lead to high administrative burdens. Even though many plans with advanced value-based care arrangements have developed generally reliable attribution processes, they rely on the essential principle of active engagement from the participating payers and providers. This differs greatly from what CMS is proposing, which is a more generic process that could include lots of instances of transient or itinerant care. A lack of provider engagement and other relationships—unlike those established in comprehensive value-based

care programs—could prove this version of a patient-provider attribution process challenging. Even with industry solutions such as the Da Vinci Project's IG for attribution, there may be several instances where a health plans' ability to evaluate a patient-provider relationship is not definitive.

ACHP foresees significant issues when determining a patient-provider relationship that warrants provider access to patient data via an API. CMS is suggesting that plans rely on proof of a scheduled appointment, but this is not enough to establish a relationship. Indeed, patients may cancel or fail to present for the initial appointment, and never return to that specific provider again. Patient-provider attribution may become even more difficult when providers in large health systems request access to patient information. Oftentimes, singular providers are not identified within health systems. For example, it is currently unclear how a health plan would grant access to a whole health system in the instance of an inpatient admission. In addition, the proposal to create an API for out-of-network providers exposes individual health data to privacy and security risks and will take more time to verify that there is a legitimate care relationship with the patient. While the rule suggests health plans leverage data from Health Information Exchanges (HIEs) to facilitate this process, there are states with HIEs that either prohibit or set high fees for access to this type of information. Some HIEs do not even contain this type of information that would be helpful and fit within the provider-patient attribution framework.

Lack of clear guidance may cause disputes between payers and providers regarding the appropriate criteria for establishing proof of relationship. These disputes could lead to unjust complaints from providers that payers are withholding or "blocking" information. This process will likely prove administratively burdensome for payers to ensure they are not providing patient information to incorrect providers and health systems. Establishing baseline minimum criteria will help advance interoperability without compromising patient privacy and trust. However, **ACHP requests that CMS utilize stakeholder feedback, such as health plans with value-based care programs and established patient-provider attribution processes, to ensure that the selected criteria is tested and appropriate.**

4. **Opt-Out**

ACHP recommends CMS change the patient opt-out provision associated with the Provider Access API to an opt-in option. Opt-out processes tend to include less active decision making than opt-in processes. ACHP is concerned patients may not understand the full extent of the opt-out process when making such decisions. This may lead to patient confusion and distrust when a patient does not realize the extent of the information they have shared with any specific provider.

Currently, making consent and exchange requests more granular on a provider/practice or informational level would be operationally challenging or infeasible. Should CMS proceed with policy proposals that require health plans to make consent granular on a provider or practice-basis, this could implicate similar challenges of practitioner-level controlled data systems. An example of this is provider directories, in which providers may operate at several locations and/or under different Tax Identification Numbers. Additionally, because USCDI contains free text elements, it would be nearly impossible for a health plan to segregate specific data to not share with providers, such as information that may be buried in progress

notes about sensitive issues like substance use disorders. Without explicitly naming these data elements, we are concerned that granular opting-out on an informational level is not feasible.

By modifying to an opt-in process for this API, patients may choose prospectively whether to allow providers to request their data from the health plan. ACHP remains committed to improving interoperability and changing to an opt-in option allows health plans to strike the balance of doing so while also maintaining patient relationships.

Payer-to-Payer Data Exchange

ACHP applauds the decision by CMS to rescind the previous payer to payer data exchange requirements and replace them with the new policy. ACHP appreciates the elimination of provider remittances and enrollee cost-sharing information from this process. We also appreciate the clarification of the data standard requirements for the Payer-to-Payer API. However, ACHP would caution CMS from suggesting that payers should assume previous payers' information is whole and/or correct, as this may lead to incorrect enrollee information that impacts care. For example, a previous provider treating the enrollee under the previous plan may have submitted incomplete information or misinterpreted medical necessity guidelines. Difference in plans' level of diligence may cause discrepancies in enrollee coverage.

Should CMS choose to finalize the Payer-to-Payer API, ACHP requests CMS consider the following:

1. **Patient Consent for Exchange**

ACHP requests additional guidance about each payers' responsibilities in payer-to-payer data exchange. Specifically, ACHP is concerned about the lack of clarity about which plan is responsible for receiving patient consent for payer-to-payer data exchange: the requesting payer or the payer receiving the request? If the responsibility is solely on the requesting payer, the payer receiving the request will still need to verify that the requesting payer obtained the patient's consent, a process that is currently unclear. Both of these procedures will require a legal process, complete with checklists, to ensure that patients understand the benefits and risks of this data exchange. These types of checks and balances are necessary to avoid non-authorized disclosures of protected health information and other HIPAA violations.

2. **Lack of Endpoint Compatibility**

ACHP reiterates our concern for endpoint compatibility and recommends CMS establish required minimum standards to eliminate the challenge. Similar to our comments about the Provider Access API, we are concerned that a lack of endpoint standardization will result in payers needing to make one-off modifications to accommodate slightly different APIs. This would mean that health plans must create customized patches for numerous health plans that chose to customize or modify the CMS recommended API standards and implementation guides. CMS should establish minimum versions or technical standards that the industry can reference, and developers can incorporate in solutions for payers.

3. **One-time Data Exchange and Timeframes**

ACHP supports CMS' proposal for a one-time data exchange between a previous and new payer but recommends CMS extend the timeframe. ACHP recognizes that there may be outlier situations or reasons why claims have not yet been processed when an initial data exchange takes place. The solution is not to require plans to send updates or change notifications as they occur. We request that CMS delay the exchange timeframe between payers to be within 30 days of the transfer to a new plan. There will likely be a lag time as a payer confirms enrollee consent to retrieve the information. This could take several days, including securing enrollee consent -- and enrollees may not respond within a reasonable timeframe. Additionally, these requests are likely to be concentrated during open enrollment; the inability to stagger these requests over time will make it more difficult to implement a one-week requirement.

4. **Patient Education**

ACHP requests further clarification on what CMS believes is the minimum necessary enrollee education that should be conveyed for payer-to-payer data exchange requests. ACHP generally supports the requirement that health plans provide enrollees with educational materials about the benefits of Payer-to-Payer API data exchange, their ability to opt in or withdraw a previous opt in decision, and instructions for doing so. However, the proposed rule lacks specificity on what the Payer-to-Payer exchange educational materials must include. In addition, ACHP would not support providing these materials more often than annually and for enrollees who have not opted-in or do not have a concurrent payer.

Patient education about the risks associated with personal health information exchange is a larger concern of ACHP's and warrants serious consideration. These interoperability provisions may have significant negative impact on consumers if left to an uneven and private sector-only education effort. Without robust, nationwide consumer education, these new tools and resources will be underutilized, despite significant investment by plans.

<u>Improvements to Prior Authorization</u>

ACHP applauds CMS for creating requirements that balance the burden on health plans with improving the prior authorization process for patients. As with the other API provisions in this proposed rule, ACHP reiterates our concerns regarding the lack of endpoint standardization. In particular, ACHP is concerned that the provider incentive will not be enough to ensure endpoint compatibility with payers' developed Prior Authorization Requirements, Documentation, and Decision (PARDD) APIs. Again, as stated with the Provider Access API, with a lack of a required standard for this API, ACHP is concerned the industry will implement this in a fragmented way and not advance interoperability.

1. **Timeframes**

ACHP requests clarifications regarding the timeframe for prior authorization request decisions. ACHP requests CMS provide examples of what qualifies as an "expedited request" and include additional guardrails to the proposal to ensure that expedited requests are submitted as appropriate. Additionally,

ACHP requests CMS consider exceptions for expedited decisions during times of high-influx or low-staffing. We encourage CMS to consider parameters for defining "high-influx" or "low-staffing" that would allow for an appropriately adjusted decision timeframe. ACHP also requests CMS provide additional information and clarification for circumstances in which an enrollee or payer may initiate an extension up to 14 additional calendar days for the prior authorization decision.

2. **Public Reporting of API Metrics**

ACHP supports public reporting requirements for the PARDD API (and the Patient Access API). ACHP agrees that the reported metrics will provide valuable insight and agrees with the annual frequency. However, we request that CMS allow plans to include further information and context to metrics in the event of an outlier. For example, ACHP requests plans have the optional ability to explain a high denial rate that may be caused by a few singular providers that consistently submit incomplete paperwork. Alternatively, ACHP requests plans to have the ability to explain approval or denial rates for services that genuinely need review, and in some cases, are not appropriate for approval. One way CMS could allow plans to provide this additional perspective is to permit them to include the total number of requests approved/denied, rather than only aggregate percentages.

3. **Phased-In Approach**

ACHP does not support the phased-in approach as described in the proposed rule and reiterates our recommendation for a phased-in approach based on the three Da Vinci implementation guides (IG). ACHP does not agree with this proposal as it will create widespread provider and enrollee confusion as to which health plan is rolling out access to the API and for what items and services. This phased-in approach also does not afford health plans the opportunity to test the Coverage Requirements Discovery (CRD) IG, Documentation Templates and Rules (DTR) IG and Prior Authorization Support (PAS) IG individually and amply. Instead, it would require all three to be established simultaneously and then troubleshoot together with the first phase.

ACHP reiterates our recommendation that CMS implement a phase-in that is segmented by functionalities—first requiring plans to implement the coverage requirements discovery, then the document lookups, followed by the implementation of prior authorization support services. Approaching the IGs in phases will build in the necessary time plans need while allowing for incremental value in each phase. As each phase builds on previous workflows, this approach allows for a hardening of the solution before extending too far into the next phase. This approach will make inter-system testing easier and increase the odds of success and adoption. This alternative, previously proposed both by ACHP and HITAC in response to ONC's March 2022 RFI regarding prior authorization, would allow plans to individually implement the functionalities, test them, and fix problems before proceeding to the next functionality. It also allows the information from the CRD to guide providers in populating their 278 requests, which would hopefully increase the use of that specific Standard Transaction.

4. **Gold Carding**

Some ACHP member companies are in the process of exploring gold carding initiatives, such as those structured as an "opt-in" program if a provider meets certain qualifying criteria, such as high prior authorization approval rates. This action comes directly from provider interest and the participating plans' beliefs that such a program could reduce both provider and payer burden by "fast-tracking" approval processes for certain providers. However, if CMS chooses to implement gold carding programs, these should remain voluntary. Gold carding programs can be difficult to operationalize and must be customized according to the localized provider characteristics. Additionally, they can present communication challenges with providers and patients. Keeping these programs optional will allow health plans to implement and test new practices without compromising resources.

Thank you for consideration of ACHP's comments and recommendations. We appreciate the Administration's dedication to the digital transformation of health care and the inevitable benefit this will have for consumers. Please contact Michael Bagel Associate Vice President, Public Policy at mbagel@achp.org or 202-897-6121 with any questions or to discuss our recommendations further.

Regards,

Dan Jones

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ACHP