Charles N. Kahn III
President and CEO

March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-0057-P, 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; Proposed Rule

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying public and privately held hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's and cancer services.

The FAH appreciates the opportunity to provide the Department of Health and Human Services' (the Department) Office for Civil Rights (OCR) with our views in response to the *Advancing*

Interoperability and Improving Prior Authorization Processes Proposed Rule (CMS-00578-P)[1] The FAH continues to believe in the potential of health information technology (health IT) to improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates CMS' commitment to improving interoperability and patient access to information and believes many of the policies contained in the Proposed Rule would advance those goals. The FAH also appreciates CMS's heightened scrutiny of health plans' prior authorization policies and the lack of transparency on how those policies perform. The FAH offers the below comments and recommendations to guide these efforts.

PART II.A.--C. PATIENT AND PROVIDER ACCESS APIS AND PAYER-TO-PAYER DATA EXCHANGE ON FHIR

General

The FAH supports the standardization of the prior authorization process and availability of information between payers, providers, and patients. To achieve that end, we support the proposed implementation of various APIs, including (1) the PARDD API, allowing greater transparency and efficiency in the prior authorization process for providers and patients (2) the provider access API, allowing the exchange of information between payers and providers, (3) the patient access API, allowing the exchange of information between payers and patients, and (4) the payer-to-payer API, allowing payers to access relevant content for prior authorizations and other payment purposes.

Automating and expediting these processes will allow providers to devote critical time to providing patient care, reduce administrative burdens for providers, and enable patients to view their own health information more efficiently and comprehensively. Given currently available technologies, the FAH generally supports the continued development of the FHIR framework to advance these goals. However, while the FHIR technology holds great promise if implemented correctly, it is largely untested. Given the limited real-world and operational experience and use cases with this technology, we urge CMS to recognize the lack of maturity of the FHIR technology and engage in ongoing review and oversight of the FHIR framework to ensure it provides the value and flexibility over time that is needed to support these APIs and achieve their purpose. Specifically, we urge CMS to ensure the technology is sufficiently developed and successfully tested to ensure that implementation is successful in 2026.

Finally, we also urge CMS not to finalize these interoperability proposals until stakeholders have had a chance to review and comment on the Office of the National Coordinator's (ONC's) Health IT Certification Program Updates proposed rule which is still under review at the Office of Management and Budget.

[1] Throughout these comments, we refer to the various organizations subject to the Proposed Rule – including Medicare Advantage (MA) organizations, applicable integrated plans, Medicaid managed care plans, CHIP managed care entities, and issuers of qualified health plans on the Federally-Facilitated Exchanges (QHPs) – collectively as "impacted payers," referencing the particular payer type only where a distinction is relevant.

Recommendations for Implementing Prior Authorization API Processes

Although the FAH generally supports the proposed APIs and related processes, our members also share certain concerns and recommendations for successful and meaningful implementation. While the FAH generally supports the January 2026 effective date for information exchange aspects of the Proposed Rule, there may be certain technical realities that could delay implementation of certain components of the Proposed Rule. Work will be required on the provider side in order to interact with the payer APIs. To allow providers the best chance to complete this development work prior to the necessary effective dates, the FAH urges that CMS partner with ONC to establish standards or other guidance for health IT developers to support providers, for example, enabling a semantic standard to utilize as a unique identifier for payers (such as a standard similar to the CMS Certification Number (CCN) associated with hospitals.) However, as discussed further below, given the importance of transparency and care for patients in the prior authorization process, to the extent there is need to delay full effectiveness of the technological aspects of the Proposed Rule, the FAH encourages CMS to proceed with the policy components of the Proposed Rule, such as the procedural and substantive requirements for prior authorization denials and reporting requirements.

The FAH also recommends that CMS adopt several implementation specifications regarding the PARDD API concerning: (i) reasons for denials of prior authorizations, (ii) the timeframe for denials, and (iii) the enforcement of those timeframes; as well as those relating to payer reporting of API metrics and payer-to-payer APIs.

Reasons for denials of prior authorizations: In order to create the desired transparency between payers and providers, the FAH urges CMS to require specificity in a payer's denial of a prior authorization request. To provide meaningful information to the provider, the payer's API should include the criteria it will use to judge an authorization request. If the payer system accepts the authorization, it should be required to include the authorization number rather than the reference number. In our member's experience, payers often provide the reference number, which does not necessarily indicate approval. On the other hand, if the payer denies a request, it should be required to provide a specific reason for the denial and should list the specific rule(s) or regulations(s) that are the basis for the denial. Otherwise, payers could rely on a generic response that is not actionable, resulting in wasted time. Up-front clarity on the payer's determinative factors will assist in alleviating the administrative burden on providers and result in fewer future denials. The automation and specificity of reasons for prior authorization acceptance or denial should likewise allow payers to process these requests more quickly.

Timeframe for denials: We appreciate the Proposed Rule's acceleration of payers' turnaround times. However, to facilitate efficient patient care, we recommend significantly reducing the turnaround time. ***Generally, the FAH urges CMS to finalize timeframes of no more than 72 hours for standard decisions and no more than 24 hours for expedited decisions. However, CMS also should consider that there are often instances when 24 hours for an expedited request would compromise and create a gap in a patient's continuity of care, and these requests should be determined within a few hours.*** For example, a psychiatric patient may need immediate authorization, otherwise they may not return to their provider for the care they need, which could harm the patient or result in the patient ending up in the emergency room

which could have been avoided with a timely authorization. ***With the PARDD API and greater interoperability between payers and providers, as well as a clear rubric from payers for criteria and denials, payers should be able to meet accelerated processing times. within mere hours of a request.***

Further, it is important that CMS clarify the triggering events for these timelines. For example, payers may disagree on whether the clock starts upon their initial receipt of a prior authorization request or at the time the payer has received any follow-up information necessary to process the request. Uniformity and clarity of the payer's criteria and expected response timeline will enable providers to better manage patient care.

Timeline enforcement: Even with clarity in the rules and turnaround times, the FAH notes the need for CMS enforcement of these timelines, without such payers have no incentive to meet the respective timeframes, resulting in delayed care for patients, which may be particularly damaging for urgent requests. The FAH encourages CMS to consider effective penalties, default rules, or other mechanisms that may incentivize payers to adhere to decision timelines or even accelerate them where possible. The FAH supports a policy under which a payer's failure to meet the timeframes results in a deemed authorization that may not be denied, reviewed, or audited for medical necessity or coverage.

Payer reporting of API metrics: The FAH notes the need to incentivize payers to provide meaningful reporting of API metrics. Although we appreciate the proposal for payers to publicly report certain prior authorization metrics, we urge greater detail in the contemplated reporting. As discussed below, we recommend that CMS require payers to on prior authorization metrics for each category of items and services (*e.g.*, inpatient hospital services, inpatient rehabilitation facility services, inpatient psychiatric services) and for each of the impacted payer's plans rather than aggregated across all items and services and plans. Further, payer reports should be based on a standardized format that can be easily read and understood by patients and others, as well as documented to CMS-designed requirements such that payers are required to report meaningful information rather than potentially confusing or obscuring internal statistics.

Payer-to-Payer API: The FAH generally supports the payer-to-payer API proposal as it would relieve provider burden by removing providers as the "middleman" when patient data must be shared between payers newly or concurrently covering patients. We also support the "opt-in" framework, but highly recommend requiring payers to explicitly educate patients about this option and its benefits rather than hiding it in enrollment or explanation of benefits documentation.

However, our members share concerns regarding the content requirements and the potential to run afoul of the minimum necessary disclosure of PHI between providers and payers. Additionally, dual payers and providers may encounter duplication of data, and therefore we recommend that CMS establish particular standards that balance the interests of interoperability with the need to support and limit this data exchange to necessary patient information. CMS' partnership with ONC can help fine-tune the specifics around the Payer-to-Payer API.

Interaction with HIPAA Right of Access Provisions

The FAH appreciates the Proposed Rule's acknowledgment that patients must ultimately control the transfer of their own health information and we therefore support the ability of a patient to opt-out of having their data available through the provider access API.

As a consequence of increased API use in pursuit of enhanced interoperability, patients would be provided more access to their health information through various health applications. The FAH appreciates CMS' request for comments concerning patients' understanding of the privacy and security implications of using third-party health applications. As we have noted in previous comment letters, we agree that it is an individual's decision to specify where and to whom to send their health information. However, many individuals routinely do not read the entire terms of use or privacy policy on the websites or mobile applications with which they interact, often making assumptions about the privacy and security of their own information.

Health care providers, on the other hand, are familiar with the HIPAA Rules and believe they provide important protections for both patients and providers regarding the exchange of protected health information (PHI). Most third-party applications, however, are not governed by the HIPAA security and privacy requirements. FAH members are concerned that these applications could expose their electronic health records (EHRs) to malware, hacking, and data mining. Hospitals must be empowered to protect their systems from unproven and potentially harmful applications and, as such, should not be considered "information blocking" for forgoing relationships with questionable applications.

In addition to security concerns, the FAH cautions CMS (and ONC) against allowing these unvetted, non-HIPAA-covered, third-party applications fairly open access to patient digital health data without patients fully understanding how those applications might use that data and the implications of that usage. The rules and processes that govern and protect digital health data must be sensitive to the reality that not all covered entities, business associates, and third parties are created equal. Particularly regarding entities that fall outside of the HIPAA requirements, it is imperative that patients, their families, providers, and consumers can trust that these applications – and the data both sent to and received from them – are secure, private, and clinically sound.

The FAH supports innovation in the marketplace while also ensuring the security, privacy, and clinical efficacy of third-party applications through patient education. We encourage CMS to undertake a joint effort among ONC, OCR, and the FTC to educate patients about the differences between HIPAA and non-HIPAA-covered entities, and how those differences may affect the ways in which their data is used, stored, and disclosed to third parties.

The FAH is aware, however, that patient education alone is not enough. We request CMS' continued collaboration with health IT developers to develop a set of best practices for development and security of these apps. In particular, we urge CMS to develop guidance concerning plain language notices and disclaimers provided to patients when the patient authorizes use of a third-party health app to store or transfer their health information. In order for such guidelines to be meaningful, we further recommend an industry-backed process to

independently vet third-party applications to ensure they are: (a) meeting all relevant security standards; (b) using data appropriately and in line with consumer expectations; and (c) clinically sound (for those applications that offer medical advice). The vetting process should be at the application level, not just at the entity level; the results of such vetting process should be made public in the form of an application "safe list"; and health care providers and API vendors should be able to refuse to connect to non-vetted applications.

Security: In order to "pass" the vetting process, an application must meet the most current security standards.

Privacy/Data Usage: The vetting should also examine applications' data usage as compared to the more stringent HIPAA requirements and then publicly report those findings for consumers in an easy-to-understand format, such as a simple comparison chart. The FAH also recommends the assignment of an easy-to-understand letter grade (e.g., A, B, C, etc.) to each application based on its data usage, with an "A" grade signaling HIPAA-level protections. The chart and the letter grade would appear to consumers prior to downloading the application or authorizing it to access their health information. This process would enhance consumers' control over their designated record set by enabling them to make fully informed decisions about where to send that data.

Clinical Soundness: Applications that contain a clinical component would undergo additional vetting to ensure they are clinically sound. The vision for the future includes health care providers pulling information from third-party applications used by their patients and then using that information to make treatment decisions. That vision is only possible if health care providers – and their patients – can trust the integrity of that information.

Publicly Reported "Safe List": The vetting organization should publicly report the third-party applications that "pass" vetting for security (and clinical soundness, if relevant) as "safe" for vendors and health care providers to connect to their APIs.

Information Blocking Exception: The FAH strongly believes that all applications seeking to connect to a health care providers' APIs must undergo this vetting process and that providers and API vendors that refuse to connect to non-vetted applications should not be considered "information blocking."

The vetting and public reporting process detailed above will go a long way toward ensuring trust while removing the burden of vetting from consumers, health care providers (API Data Providers), and API Technology Suppliers, while empowering patients to better control their information and drive their care.

PART II.D. IMPROVING PRIOR AUTHORIZATION PROCESSES

We applaud CMS' recent attention to the issue of prior authorizations, and we share CMS' concern that "the prior authorization process is a primary source of burden for both providers and payers, a major source of burnout for providers, and ***can become a health risk for patients if inefficiencies in the process cause care to be delayed***." Our members have experienced many of the challenges highlighted by the CMS and ONC work group that studied

prior authorization: In particular, our members experience "difficulty determining payer-specific requirements for items and services that require prior authorization; inefficient use of provider and staff time processing prior authorization requests and information (sending and receiving) through fax, telephone, and web portals; and unpredictable wait times to receive payer decisions." In short, prior authorization is a burdensome process that diverts provider resources away from patient care and, at worst, may prompt patients to delay or forego needed care.

We applaud CMS' efforts to put patient care first by proposing needed process improvements and transparency initiatives around impacted health plans' use of prior authorization. At best, prior authorization processes can provide patients with the financial security that comes from knowing that their care will be covered, but our members have observed that prior authorization processes are often unnecessarily burdensome and can risk inappropriate delays in patients obtaining the care to which they are ultimately entitled under their health plan or benefit program. As highlighted in the April 2022 report by the Office of the Inspector General (OIG) regarding prior authorization practices by MA organizations, prior authorization requests are too frequently denied even in circumstances where the applicable Medicare coverage criteria had been satisfied such that the beneficiary was actually entitled to coverage for his or her care.[2] Transparency is critical to hold health plans accountable for practices that impact patient access to covered benefits (including prior authorization and other utilization management activities) and to allow patients to make informed choices regarding their enrollment and coverage. Therefore, as explained further below, the FAH strongly urges CMS to impose reporting and disclosure requirements that will provide both CMS and consumers with greater insight into impacted payers' use of prior authorization.

Part II.D.4 Reasons for Denials

The FAH supports CMS's proposal to require impacted payers to "provide a specific reason for denied prior authorization decisions . . . regardless of the method used to send the prior authorization request," (87 Fed. Reg. at 76,292), but urges CMS to clarify that the impacted payer is obligated to provide each specific reason for the denial. Where there is more than one reason for a denial, providing each reason is of critical importance so that the provider may evaluate whether it would be appropriate to resubmit with additional information, appeal the determination, or take other action. Without full communication of the reasons for a denial, providers face a piecemeal process in which new, alternative reasons are first identified after the provider takes action to address the disclosed reason for denial. This approach is unnecessarily burdensome and inappropriately prolongs the prior authorization process, to the detriment of patients and their care teams. The FAH therefore urges CMS to require each impacted payer that denies a prior authorization request to identify *each* reason for the denial so that the provider receives adequate information regarding, as applicable, each eligibility, coverage, medical necessity, or other issue supporting the denial along with the specific details of criteria that were not met (if any). This could be made clearest by revising the last clause of proposed 42 C.F.R. § 422.122(a)(2), 42 C.F.R. § 431.80(a)(2), 42 C.F.R. § 457.732(a)(2), and 45 C.F.R.

[2] OIG, Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care (April 2022), *at* https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

§ 156.223(a)(2) to read as follows: "the response to the provider must include **each** ~~a~~ specific reason for the denial." This will give the provider and patient the opportunity to fully evaluate appropriate next steps and promotes the efficient resolution of prior authorization issues.

Part II.D.5 STANDARD TIMEFRAMES AND NOTICE REQUIREMENTS FOR ORGANIZATION DETERMINATIONS

The FAH supports CMS' proposal to align the timeframes by which the impacted payers should respond to prior authorization requests as closely as possible without undue burden on QHPs, but has significant concerns that the proposed timeframes—72 hours (for expedited decisions) and 7 days (for standard decisions)—are too long, creating unnecessary risks that patients will delay or forego necessary care or will remain in the acute care environment long past the time when they are ready to transition to post-acute care. ***Instead, the FAH urges CMS to finalize timeframes of no more than 72 hours for standard decisions and no more than 24-hours for expedited decisions.***

The FAH believes that timeframes far shorter than those proposed are feasible, even without the benefit of the PARDD API, and would appropriately reflect the importance of providers and patients receiving prior authorization decisions as expeditiously as possible. In fact, some states impose prior authorization requirements that are similar to the alternatives considered in the Proposed Rule—"48 hours for expedited requests and 3 days for standard requests." 87 Fed. Reg. at 76,347. As an illustrative example, Arkansas utilization review entities are required to render prior authorization decisions within one business day (expedited requests) or two business days (nonurgent services) of receiving all necessary information (Ark. Code Ann. §§ 23-99-1105 -1106). In Maine, standard prior authorization requests must be decided within 72 hours or 2 business days, whichever is less (Me. Stat. tit. 24-A, § 4304(2)), and in North Carolina prior authorization decisions are required within three business days (N.C. Gen. Stat. Ann. § 58-50-61(f)). ***In light of these currently effective state law requirements, the FAH believes that it would be feasible for impacted payers to respond to prior authorization requests within no more than 72 hours (standard) or 24 hours (expedited), even using existing prior authorization processes, and that the patient experience of care would be inappropriately compromised by longer timeframes.***[3]

In addition, the FAH fully supports CMS' reevaluation of these timeframes as streamlined prior authorization processes create efficiencies that "would make shorter timeframes more feasible." 87 Fed. Reg. at 76,347. ***In particular, as discussed above regarding "Recommendations for Implementing Prior Authorization API Processes," the FAH believes that an efficient prior authorization process (including one that uses the PARDD API) would allow for an expedited prior authorization decision to be issued within mere hours of a request.***

[3] With respect to individual and group market plans that are not QHPs, the FAH also urges CMS to coordinate with the Departments of Labor and Treasury to undertake appropriate joint rulemaking imposing prior authorization timeline requirements for these insurers and plans that mirror those finalized for impacted payers.

We also urge CMS to establish corresponding notification requirements to ensure that both the enrollee *and* the requesting provider receive notice from the impacted payer of the prior authorization decision in the same timeframe. Our members report confusion when their patients receive prior authorization denials after the denial has been successfully overturned—and sometimes even after services have been rendered. Uniform timing for patient and provider notices would effectively avoid such confusion.

Finally, the FAH is concerned with the lack of an efficient process for addressing impacted payers' failure to comply with the proposed prior authorization timeframes. The Proposed Rule indicates that, "[i]f a payer fails to meet the timeline for approval or other decision, providers should contact the payer to obtain the status of the request and determine if supporting documentation is needed to complete processing of the authorization or if there are other reasons for the delay in a decision."[4] 87 Fed. Reg. at 76,297. This approach inappropriately shifts the impacted payer's administrative obligation to timely process prior authorization requests to already over-stretched providers who should be focused on their patients' care and prolongs the process well beyond the regulatory timeframes. ***Instead, the FAH supports a policy under which a payer's failure to meet the prior authorization timeframes results in a deemed authorization that may not be denied, reviewed, or audited for medical necessity or coverage. Such an approach creates appropriate incentives for impacted payers to diligently track and process prior authorization requests and minimizes the burden of payers' non-compliance with prior authorization requirements, and we disagree with CMS's suggestion that such a policy is not practical.*** *Id.* Rather, a deemed compliance policy is an effective mechanism to discourage non-compliance with critical timelines, and we urge CMS to require impacted payers to treat as granted all prior authorization requests for which the payer has failed to provide a timely determination.

Part II.D.8 PUBLIC REPORTING OF PRIOR AUTHORIZATION METRICS

We agree with CMS that "publicly available data would aid interested providers and patients to generally understand payer performance with respect to prior authorization processes for decisions, approvals, denials, and appeals." 87 Fed. Reg. at 76,305. ***Therefore, the FAH applauds CMS' proposal to promote transparency by requiring impacted payers to publicly report metrics about their prior authorization processes at the plan level beginning in 2026, but also urges CMS to (1) require direct reporting of these metrics to CMS and other regulators in order to facilitate regulatory oversight and (2) require disaggregation of metrics for each plan offered by the impacted payer and for each category of items and services to avoid the obfuscation of critical disparities in access to covered benefits.*** On the first point, the FAH is concerned that public reporting of prior authorization metrics without direct reporting to regulators does not adequately facilitate regulatory enforcement of the prior authorization requirements. In addition, direct submission of the data to CMS may promote more careful diligence among impacted payers with respect to the validation of the prior authorization performance data. FAH members, for example, report that some payers merely supply tracking

[4] As noted in the Proposed Rule, for some impacted payers (*e.g.*, MA organizations) the failure to provide timely notice in response to a prior authorization request may also be an adverse decision subject to immediate appeal. 87 Fed. Reg. at 76,297.

numbers in lieu of decisions within the regulatory timeframe for prior authorization decisions. Improperly conflating the tracking number with the prior authorization decision would skew reported data on the average and median time that elapsed between the submission of a request and a determination for standard and expedited prior authorizations, creating consumer confusion and diminishing the value of the data. Direct reporting of the data to CMS would, however, incentivize impacted payers to validate and verify the data before submission so that data would be more likely to provide consumers with reliable and actionable information.

With respect to aggregation, the FAH urges CMS to require reporting on prior authorization metrics for each category of items and services (*e.g.*, inpatient hospital services, inpatient rehabilitation facility services, inpatient psychiatric services) and for each of the impacted payer's plans rather than aggregated across all items and services and plans. Aggregation of prior authorization metrics across items and services will result in high volume prior authorization requests obscuring data around other critical items and services and diminishing the value of the data for consumers. In contrast, more granular reporting would reveal, for example, whether the impacted payer denies prior authorization requests for high-intensity and time-critical items and services like inpatient rehabilitation at disproportionately high rates. These are precisely the practices that the OIG highlighted in its April 2022 report (at p. 14), voicing the concern that MA organizations may "have an incentive to deny more expensive services" in an effort to "reduce their costs." Without item- and service-level reporting, it will be impossible for CMS and the public to understand whether an impacted payer's prior authorization practices are disproportionately affecting enrollees with specific needs and to hold impacted payers accountable for excessive denials and delays in responding to prior authorization requests.

Along similar lines, the FAH supports reporting at the contract or plan level for MA organizations, Medicaid and CHIP managed care, and QHP issuers. At present, the Proposed Rule would only impose plan-level reporting for Medicaid and CHIP managed care plans "so that beneficiaries could compare and states could evaluate plans within the state." 87 Fed. Reg. at 76,304. This same rationale supports reporting at the plan level for other impacted payers. To the extent that a MA organization's or QHP issuer's prior authorization practices are consistent across its contracts or plans, consumers and regulators would see largely consistent data reported for each of the MA organization's contracts or plans offered by the QHP issuer. But, if there are differences across plans and contracts—which might occur if, for example, a delegated entity performs prior authorization functions under one MA organization contract but not another—presenting the data at the MA organization or QHP issuer level means that consumers and regulators would be unaware of those differences and less able to make informed choices.[5]

Lastly, the FAH does not believe that full implementation of the PARDD API is necessary to allow impacted payers to fully comply with these public reporting requirements. The FAH strongly supports an earlier reporting applicability date – possibly as early as 2024

[5] The FAH notes that CMS "considered reporting these metrics at the parent organization" level for all impacted payers, and strongly supports CMS's conclusion that reporting at the parent organization level would "be too aggregated a level of reporting for some payer types to provide useful information for patients and providers." 87 Fed. Reg at 76.347.

or six months after publication of a final rule – for prior authorization metric reporting given the significant need for greater transparency around prior authorization practices and performance. Transparency both enables consumers to make informed coverage decisions and appropriately incentivizes impacted payers' investment in the processes necessary to produce timely and accurate prior authorization decisions. ***If CMS maintains its proposed 2026 implementation date for reporting prior authorization metrics, that date should remain in place even if the timing of other elements of the Proposed Rule, such as the interoperability provisions, are for some reason delayed.***

In sum, the FAH urges CMS to adopt the proposed reporting requirements to be applicable beginning as early as January 2024 or six months after publication of a final rule; to expand these reporting requirements to include direct reporting of the data to CMS along with the proposed public disclosure; to require impacted payers to report each set of information identified in paragraph (c)(2), (c)(3), (c)(4), (c)(5), (c)(6), (c)(7), (c)(8) and (c)(9) for each category of items or services; and to report at the contract level (MA organization) or plan level (Medicaid and CHIP managed care and QHP issuers).

Part II.D. PRIOR AUTHORIZATION ENFORCEMENT & ACCOUNTABILITY MECHANISMS

The FAH supports the prior authorization process improvements set forth in the Proposed Rule, with the refinements set forth above, but also strongly urges CMS to prioritize enforcement and impacted payer accountability with respect to prior authorizations. Although providers and patients can challenge or appeal an impacted payer's inappropriate denial of or failure to act on a prior authorization request, pursuant to contract, regulation, or both, the availability of internal and external review processes and further appeals is insufficient to promote prior authorization processes that are effective from the standpoint of either patient care or burden reduction. These one-off challenges are burdensome and time-consuming, such that appeals likely represent just a fraction of improper prior authorization denials. The availability of these appeal mechanisms does not change the fact that certain impacted payers may engage in a pattern and practice of inappropriately denying prior authorization requests, as observed by the OIG in its April 2022 report. Against this backdrop, the FAH is concerned that such practices will not be sufficiently checked by transparency around prior authorization metrics and thus urges CMS to use its enforcement authority to tackle inappropriate utilization management practices head-on.

To that end, the FAH recommends that CMS undertake rulemaking to expand its oversight and enforcement mechanisms. In particular, we urge CMS to consider:

- Expanding public reporting by impacted payers to include direct reporting to CMS with sufficient granularity (*e.g.*, by each category of item and service and for each plan or CMS contract, as applicable) to provide insight into the particular services for which prior authorizations are routinely delayed, denied, and/or overturned, disaggregated by payer type.
- Engaging in routine audits of impacted payers to assess compliance with prior authorization requirements, including the timeliness of decisions and accuracy and completeness of public reporting of prior authorization data.

- Imposing sanctions for the inappropriate use of prior authorization processes to deny or delay coverage of services.
- Developing quality measures for the various quality star rating programs (*e.g.*, for MA organizations and QHP issuers) reflecting the timeliness of prior authorization decisions and the rates at which prior authorization denials are overturned.

Part II.E. ELECTRONIC PRIOR AUTHORIZATION FOR THE MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS) PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY AND THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM

CMS is proposing to require eligible hospitals to report on an electronic prior authorization measure under the Medicare Promoting Interoperability Program to incentivize the use of API functions for prior authorization by providers. In general, the FAH supports CMS' efforts to improve the uptake of electronic prior authorization processes and agree that the health information exchange (HIE) objective of the Medicare Promoting Interoperability Program is the appropriate placement for such a measure. However, we recommend revising the measure specification language to provide more clarity to eligible clinicians and hospitals. We note that developing the technology to meet this measure requirement will impose burden on providers but believe the measure will ultimately provide an excellent opportunity for providers and payers to meet in the middle on electronic prior authorizations.

Attestation

We support the proposal to exclude this measure's performance in the composite score for both the MIPS and Promoting Interoperability Program for the first year. However, we note that requiring numerator and denominator attestations appears stricter than the direction CMS has taken in recent years. Alternative measures within the HIE objective, such as the PDMP, Bi-Directional Exchange, and TEFCA measures, all require 'yes or no' attestations. We recommend aligning this new electronic prior authorization measure's reporting requirements with these other measures, especially while technology and adoption are both nascent.

Clarifications

We recommend that CMS clarify a few components of this new measure. First, CMS should revisit some of the terms used in the measure specification. For example, if clinicians or hospitals intend to achieve prior authorizations through CEHRT, would supplementary actions such as phone calls or faxes, especially if the payer requires them, exclude them from the numerator? Moreover, how many of these administrative actions would disqualify a prior authorization for this measure?

Additionally, individual providers do not often perform their own prior authorization workflows alone. Office staff assist in gathering documentation and assisting with medical equipment fittings. Would these supportive actions not be included in the numerator? Providing

additional guidance or more explicit language around these components would relieve interpretation burden on providers seeking to comply with this measure.

Second, the Bi-Directional Exchange measure has created greater opportunities for sharing health information electronically. Placing the prior authorization measure under this objective makes sense. However, we request additional clarification on the expectations for incorporating such workflows into the Medicare Promoting Interoperability Program. We suggest clarifying whether or not hospitals and providers are expected to begin to share prior authorization information via the integrations with health information networks as a means to meet the bi-directional HIE measure.

Exclusions

We appreciate the noted exclusions for this measure but request clarification on Exclusion 2. We realize that some payers may not have a fully implemented PARDD API for use in the PI Program by the time providers begin the reporting period. In the case that payers deliver their PARDD API during a reporting period, would providers need to begin requesting prior authorizations for ordered items or services immediately? We recommend that CMS provide allowances or a grace period similar to the public health measures, in which providers have six months following a state's declaration of readiness to lose the ability to take this exclusion. In this case, clinicians and hospitals should still be able to use Exclusion 2 if they order items or services from a payer who has not offered the PARDD API within 6 months of the start of their reporting period.

Compliance Date

Given the development burden on providers to create technology that will be able to query payers' PARDD APIs, we suggest tying the compliance date, for reporting the new quality measure, to the publication of a final rule from CMS. While three years may provide ample development and testing time, we note the government's lengthy rulemaking process. It would be unwise to begin development work based on a Proposed Rule, so we suggest a compliance date of 36 months following publication of a final rule or one year after the implementation of APIs, whichever is later.

III. REQUESTS FOR INFORMATION

III.A. REQUEST FOR INFORMATION: ACCELERATING THE ADOPTION OF STANDARDS RELATED TO SOCIAL RISK FACTOR DATA

CMS seeks input on barriers the healthcare industry faces to using industry-wide data standards and opportunities to accelerate adoption of data collection standards related to social risk factor data, including exchange of information with community-based organizations. Unfortunately, social risk factor data are often fragmented, unstandardized, out-of-date, and duplicative. These circumstances are a result of a lack of clear standards for capturing, recording, and exchanging these data.

In general, collecting social risk and social needs data once a patient enters an inpatient setting is too late. FAH members recommend collecting social risk factor data in the community setting so needs can be addressed earlier. This will help to avoid inpatient care, in some cases. We understand this is not always practicable for the patient populations with the highest social risk, as these patients do not seek health care services until necessary. We encourage CMS to identify and coordinate with local health and social work departments to collect this information in the community setting, if possible.

Best Practices on Frequency of Data Collection

We recommend the best practice of updating social risk and social needs data at least annually, as some social risk factors may be fluid, such as socioeconomic status, food insecurity, gender identity, or sexual orientation.

Collecting social determinants of health data at admission and discharge is not the most ideal time. The most important time to collect this information is a few days prior to discharge, so case managers have time to contact any additional social support programs that may be needed. This information also should be more episode-based, and where data is collected for a patient in an acute care hospital, the information should be shared with any other providers who care for the patient during their episode of care, such as an inpatient rehabilitation facility.

CMS Support

CMS should ensure that all healthcare professionals are trained on the importance of collecting data regarding social risk and social needs, and on how to ask questions from patients in a way that is respectful, ensures privacy, and communicates the reason for asking for information. If the goal is to better understand the patient population better so that social risk factors and social needs are addressed, proper training should be encouraged that helps put patients at ease and at the same time helps reduce health disparities and provide quality patient care.

The FAH also would encourage CMS to provide health systems and hospitals with information on how CMS is utilizing social risk data, as well as provide additional guidance to health care providers on how best to use this data after collection.

Screening Tools

FAH members see the following challenges in our current ecosystem regarding representing and exchanging social risk and social needs data from different commonly used screening tools:

- Patient privacy across systems and lines of business.
- Consistency of field labels and available fields to collect data.
- Fluid identities (i.e., socio-economic status, housing status, sexual orientation, gender identity, pronouns), and updating fields when information changes.
- Updates in one system may not communicate the updates to other systems (interoperability).

Screening tools generally are more applicable to the general acute care setting, and post-acute facilities have a hard time with the scope of the tools, in that they do not see certain patient populations, such as maternity care. In addition, many questions are too complicated and do not lend themselves to a "yes/no" answer. Yet, some systems have designed tools de novo, that are 'yes/no' based to help case managers with follow-up. Screening tools can be useful, however, we caution CMS to consider how information will be electronically coded to provide useful, actionable data without overcomplicating the questions.

Privacy Issues

CMS should consider data privacy concerns on how information is collected and shared, as the patient may have concerns about experiencing discrimination in certain spaces or with disclosing information -- whether with healthcare providers or government entities. Social risk and social needs information can be incredibly sensitive, and there should be a requirement that permission is explicitly given to collect this information from patients. Training also is needed to mitigate bias of those accessing the data/information and interacting with the patient. Specialized training to understand the purpose of the data and identify the health disparities that the patient may experience based on the information provided is needed. Additionally, training in cultural competency is needed for providers to know how to identify and address the health disparities represented by the data.

Coding

Some hospital systems use EHRs to capture, exchange, and use social risk and needs data. This information crosses other lines of business and patient care spaces. Challenges include the ability to understand additional data behind claims codes, such as why a medical service was refused, which may have been because of income or because of religious beliefs (e.g., refusing blood transfusions). The reason behind the claim code is not always represented in the data. Further, there is not a uniform standard, or even a standard set of codes for collecting this information between all healthcare providers, which needs to be addressed.

Strategies to Consider

CMS can play an important role in preventing bias and stigmatizing language within EHRs and support the healthcare community with the following strategies.

First, the healthcare community can offer providers and clinicians implicit bias education that creates the opportunity for self-awareness; educates on health disparities caused by systemic racism, classism, sexism, ableism, and other forms of oppression; advances nondiscrimination; and provides mechanisms and strategies to counter the use of biased cognitive shortcuts and stereotyping that result in use of negative patient descriptors.

Second, we can provide clinical education on the use of people-first language and non-stigmatizing language, including strategies to prevent the perpetuation of negative descriptors in the medical record. We can emphasize the importance of patient/person-centered care and the

need for clinical empathy in considering how negative descriptors can undermine the provider-patient relationship, patient satisfaction, health outcomes, and potentially lead to litigation.

Third, CMS can support adopting professionalism and professional communication best practice standards of the Accreditation Council for General Medical Education.

Fourth, health systems should evaluate and remediate structural factors that enable or exacerbate bias and use of negative descriptors, including factors that contribute to provider and clinician burnout and stress.

Fifth, a longitudinal record of social risk and social needs data, as well as a patient's health would be very beneficial. The information should be collected at the community-level with community health centers, health clinics, case managers, and health departments.

And finally, the healthcare community must recognize artificial intelligence technologies are not a protective factor: AI technologies and data systems should be scrutinized for ways that they perpetuate stereotyping. We encourage CMS to consider these strategies to prevent bias.

Remaining Opportunities

CMS should encourage adherence to Web Content Accessibility Guidelines (WCAG) on digital platforms, as this also creates barriers for patients with disabilities. Ensuring patient portals are compliant with Section 1557 of the Patient Protection and Affordable Care Act and adhere to Web Content Accessibility Guidelines makes access for persons with limited English proficiency and persons with disabilities possible.

IIIB. REQUEST FOR INFORMATION: EXCHANGING BEHAVIORAL HEALTH DATA

CMS is seeking comments on how it might best support electronic data exchange of behavioral health information between and among behavioral health providers, other health care providers, and patients, to improve care and treatment for individuals with behavioral health needs. CMS also is interested in evaluating whether using other applications that exchange data using the FHIR APIs and do not require implementation of a full EHR system might be a way to help behavioral health providers leverage technology to exchange health data to improve care quality and coordination.

Several factors have led behavioral health providers to adopt EHRs at a significantly lower rate than other types of health care providers. One key contributing factor was that the Health Information Technology for Economic and Clinical Health Act (HITECH Act), enacted as part of the American Recovery and Reinvestment Act of 2009, made Medicare fee-for-service and Medicaid incentive payments for the adoption and meaningful use of certified EHR technology (CEHRT) available only to eligible professionals, eligible hospitals, and CAHs, so behavioral health providers that did not meet those criteria were ineligible for these incentive payments. For example, while behavioral health providers who were physicians (eligible professionals) could receive the incentive payments, inpatient psychiatric facilities (IPFs) were

not eligible. Other regulatory restrictions which govern the confidentiality of substance use disorder patient records maintained by certain entities, or more restrictive state laws, can also inhibit the exchange of behavioral health information.

The absence of broad adoption of EHRs and data exchange by behavioral health providers makes the prior authorization process even more challenging. Behavioral health providers face the same obstacles and challenges when trying to get prior authorization approval to address the inpatient and outpatient behavioral health needs of their patients.

Exchanging Behavioral Health Data

Today, behavioral health providers and IPFs lag behind their peers in the ability to electronically share health information across providers and with patients. We share CMS' concern about the lack of electronic exchange of information in the behavioral health provider community and the gaps that exist in care coordination via electronic information exchange. Although several obstacles exist for this type of data exchange, our primary concerns are low EHR adoption (primarily due to lack of incentive payments); the lack of standards to support behavioral health data exchange; and fragmentation among behavioral health care providers seeking to exchange data under differing privacy constraints.

EHR systems are expensive and require vendor support for implementation. We urge CMS and the Center for Medicare & Medicaid Innovation (CMMI) to pursue models that could spur EHR adoption. Congress created a potential opportunity to address this issue when it enacted the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) in 2018. Section 6001 of the SUPPORT Act modifies an existing list of possible model opportunities CMMI may consider testing to provide incentive payments to behavioral health providers for adopting EHRs. We urge CMMI and CMS to actively engage IPFs and other behavioral health providers in developing potential models that could spur EHR adoption and exchange of clinical information – including through the use of FHIR APIs.

Standards

Additionally, meaningful exchange of behavioral health data also requires adoption of data and exchange standards. We support CMS' consideration of FHIR APIs and the promise they hold for more agile, targeted data exchange. Health care providers have seen the benefits of FHIR among federal healthcare entities, such as the US Department of Veterans Affairs providers and the Defense Health Agency. We recommend a phased approach to setting standards for behavioral health data exchange or even a minimum, core dataset to initiate a phased approach.

Privacy Laws

Finally, a chief hurdle to exchanging behavioral health information is the disjointed landscape of privacy laws and consent requirements for such exchange. This affects mechanisms from third party APIs to non-covered entities providing behavioral health services. CMS could

focus new efforts to elevate behavioral health data exchange with supporting standards and clarifying guidance for acceptable "best practices" for organizations and providers caring for patients across state lines and when consent laws conflict.

D. REQUEST FOR INFORMATION: ADVANCING INTEROPERABILITY AND IMPROVING PRIOR AUTHORIZATION PROCESSES FOR MATERNAL HEALTH

The FAH applauds the Administration for the prioritized addressing of the nation's maternity care crisis. We support the *Call to Action* to improve maternal health outcomes across the United States. First, with the release of the White House Blueprint for Addressing the Maternal Health Crisis in June 2022 and subsequently the release of the CMS Maternity Care Action Plan in July 2022.

Despite these efforts, the effects of inefficient prior authorizations on maternal health are noteworthy. For instance, maternal care experts have observed that some payers may utilize an intermediary, such as a radiology benefits management company, to act on their behalf to review healthcare provider requests to perform imaging. This may add an additional waiting period for a decision, potentially creating hazardous delays for pregnant women who, for example, need to obtain an ultrasound.

FAH members believe patients should experience a more simplified prior authorization process in maternal healthcare. Maternal health providers provide emergent care, and unfortunately, almost always receive the authorization approval after the fact. Therefore, we recommend a more congruent process that would allow providers and their patients to receive approval prior to a procedure being administered for maternal care.

In perinatal medicine, the largest impact has been for patients in need of specialized procedures. There are only a few high-quality fetal therapy centers around the country. For example, Virginia's Medicaid will not approve a service out-of-state if the same service is available in-state. Unfortunately, some of the in-state service availability may be less skilled and thus provide lower quality in a particular procedure or diagnosis. A more robust federal program can help solve this problem.

The FAH also strongly encourages CMS to allow previously approved prior authorizations for maternal care to carry over from one payer to another when a patient changes payers during the pregnancy. This will greatly support continuity of care and provide a seamless experience for the mother and her baby.

Lastly, we see a great benefit in linking maternal and neonatal data in support of improved maternal health transitions. Collaborating with ONC to create standards to support this linkage would enhance data accuracy while sharing data for maternal health.

E. REQUEST FOR INFORMATION: ADVANCING THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT (TEFCA)

The FAH believes that cohesiveness in health IT management can improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. The FAH appreciates CMS' leadership efforts to further the exchange and use of health information and offers the below comments in response to the TEFCA RFI.

Advancing the Use of TEFCA

The FAH and its members are committed to furthering TEFCA's goals in establishing a universal policy for interoperability, simplifying connectivity for organizations to securely exchange health information to improve patient care and access to information. As TEFCA is still in early implementation stages, it needs to be tried and tested before being widely adapted to other CMS programs.

In the meantime, however, the FAH encourages participation in TEFCA so that when it has matured and is ready for implementation, it is agile enough to support other programs. TEFCA ultimately could help advance the goals of several CMS programs and could create a floor for interoperability across these programs. We appreciate its inclusion in the Medicare Promoting Interoperability Program for eligible hospitals and recommend it as an option for Merit-based Incentive Payment System (MIPS) eligible clinicians and other quality payment or value-based care programs. Other payer programs, such as MA, also could benefit from TEFCA engagement by reducing expensive encounters.

In addition, we encourage CMS to consider establishing a public health Qualified Health Information Network (QHIN) to participate in TEFCA. Such a QHIN could create the needed infrastructure to support public health reporting required by CMS programs and ease the significant burden that working with multiple state public health agencies causes providers.

CMS should explore policy and program mechanisms to encourage exchange between different stakeholders, primarily between providers and payers. We recommend that CMS require standardized clinical content and methods of delivery for all data sets. Consistent requirements for all CMS-regulated groups would increase transparency, provide minimum necessary guardrails for data exchange, and ease burden for several use cases, namely prior authorizations. We also recommend that CMS evolve these data sets in alignment with the ONC Standards Version Advancement Process (SVAP) so that the healthcare community exchanges data in a more structured way. With any CMS-sponsored use of TEFCA, a uniform approach would "right-size" the clinical content needed for a particular service or purpose, increasing healthcare efficiencies and targeted care.

The *21st Century Cures Act* seeks to reduce provider burden, promote interoperability, and advance patient access. CMS encouragement of participation in TEFCA would provide an optimal way to achieve these goals. However, in the event of any future expansion of TEFCA,

we urge CMS to provide hospitals and all stakeholders an opportunity for regulatory notice and comment.

Use Cases

Our members envision TEFCA supporting a variety of use cases in the healthcare community. As discussed above, TEFCA could promote interoperability initiatives and reduce provider burden via its use of structured data sets. However, CMS would need to recommend these content thresholds for information exchange for providers, payers, and others participating in CMS programs using TEFCA. This would amplify usability among health IT products, allowing greater efficiency in care delivery. The variety of methods to exchange data make it difficult for providers to find the most useful data within their technology. For example, a specialist receiving a referred patient would find it easier to extract the pertinent data for the encounter using TEFCA rather than having to review a summary of care document.

Further, TEFCA could support a variety of healthcare payment purposes. Patients, providers, and payers could all benefit from a model able to support prior authorization, utilization management, and other improvements in provider-to-payer communication.

Incentives for TEFCA Participants

Including TEFCA components in CMS programs and benefit plans would further encourage industry use. Given that TEFCA could reduce interference with access, exchange, and use of electronic health information, we recommend creating an incentive for participation involving the Information Blocking rules, such as creating a safe harbor for those active in TEFCA exchange.

Concerns with TEFCA

We applaud TEFCA's potential to accelerate interoperability across the country but recognize there are challenges with doing so at such scale. First, a chief obstacle to data exchange is patient matching. A standard patient matching approach across the TEFCA model is critical for ensuring that participants do not miss or mismatch patients. This will be vital to its maturity while ensuring confidence in patient identity resolution overall. Second, there is a lack of consistency in the availability and use of mapping terminologies and CPT codes. These inconsistencies are a barrier to true interoperability, and therefore if CMS were to advance the standardization of semantic terminologies, or license public use of highly adopted terminologies, this would be advantageous to all participants. Finally, with several entities allowed to participate in TEFCA, we are concerned with possible bad actors. Interoperable health data exchange increases efficiency but also creates the possibility that some may misuse this information. When "newsworthy" bad outcomes occur and shape public opinion, it undermines the strides taken to promote interoperability and weakens dynamic exchange. While we enthusiastically support CMS initiatives to advance the use of TEFCA, it cannot be achieved without addressing these challenges. As TEFCA continues to mature, we urge CMS and ONC to work with stakeholders to address these significant challenges.

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The FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership as we strive to advance the use of health IT to improve our nation's health care system. If you have any questions regarding our comments, please do not hesitate to contact me or a member of my staff at (202) 624-1534.

Sincerely,