Charlene K. MacDonald
President and CEO

June 15, 2026

Via electronic submission at http://www.regulations.gov

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0062-P
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges [CMS-0062-P]

Dear Administrator Oz:

As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, the Federation of American Hospitals (FAH) appreciates the opportunity to provide the Department of Health and Human Services' (the Department) Office of the National Coordinator for Health Information Technology (ONC) and the Centers for Medicare & Medicaid Services (CMS) with our comments in response to the above-referenced *Interoperability Standards and Prior Authorization Proposed Rule* (CMS-0062-P; Proposed Rule).[1]

FAH continues to believe that advances in health information technology (health IT) improve the quality and efficiency of care provided to patients, reduce provider burden, and advance population health management and breakthroughs in health care research. We appreciate CMS' commitment to improving interoperability and patient access to medically necessary drugs and believe many of the policies contained in the Proposed Rule would advance those goals. We also applaud CMS' heightened scrutiny of health plans' prior authorization (PA) policies for non-drug items and services, as well as for drugs, and the agency's continued efforts to improve transparency into how those policies perform.

Prior authorization continues to be one of the most significant administrative challenges facing patients, hospitals, physicians, and health plans. While electronic prior authorization has the potential to improve efficiency and reduce delays, successful implementation will require practical standards, provider flexibility, meaningful payer accountability, and sufficient time for hospitals and technology developers to adapt.

[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.

FAH offers comments and recommendations to guide these efforts, including key recommendations which are summarized below:

Put Patients First by Reforming Prior Authorization: Prior authorization remains one of the most significant administrative barriers affecting patient care. FAH strongly supports CMS's efforts to shorten prior authorization decision timeframes, improve communication between payers and providers, and increase transparency regarding payer utilization management practices.

Standardize Prior Authorization Processes and Timelines: To further improve patient access, CMS should standardize prior authorization response timeframes across payer types, require concurrent notification of providers and patients, and establish meaningful consequences when plans fail to meet required deadlines.

Improve Transparency and Accountability: FAH supports CMS's proposals to expand public reporting of prior authorization metrics and to require payers to provide specific reasons when requests are denied. For more meaningful transparency that will better inform patients and providers, CMS should require payers to report more detailed information by plan and by each service category (such as inpatient or outpatient care, inpatient rehabilitation services, or inpatient psychiatric services) so that regulators, patients, and providers can identify patterns of inappropriate delays or denials.

Strengthen Oversight and Enforcement: CMS should enhance payer compliance through audits, enforcement activities, and accountability measures that discourage inappropriate utilization management practices and ensure plans comply with prior authorization requirements.

Advance Interoperability Through Practical and Flexible Implementation: FAH supports the use of modern interoperability standards, including FHIR-based technologies, to facilitate electronic prior authorization and improve information exchange. To ensure successful implementation, we recommend:

- Ensuring provider flexibility, such as avoiding policies that would effectively require every transaction to occur through certified electronic health record technology.
- Sufficient testing, operational experience, and flexibility for organizations that rely on legacy systems that currently do not support a FHIR standard.

Support a Strong National Interoperability Infrastructure: FAH supports CMS's proposal to require publication of payer API endpoint information and encourages the agency to establish a centralized national registry to simplify connectivity and reduce administrative complexity. Reliable endpoint discovery is essential to creating scalable, nationwide interoperability.

Support National Patient Matching Standards: FAH supports industry-led, scalable and flexible national patient matching standards that improve interoperability and patient safety through standardized demographic data and better matching accuracy. We recommend that CMS work with ONC and other federal partners to develop more specific national guidance for patient matching across the interoperability ecosystem.

Strengthen Cybersecurity While Avoiding Unnecessary Burden: FAH supports CMS's efforts to strengthen cyber resiliency and urges the agency to adopt risk-based approaches, aligned across existing federal privacy laws, that recognize differences among providers, avoid duplicative regulatory requirements, support shared accountability across the health care ecosystem, and allow organizations to focus resources on the most significant risks to patient care and operational continuity.

FAH appreciates the opportunity to comment on the Proposed Rule. We look forward to continued partnership as we strive to strengthen prior authorization processes and transparency and 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) 624-1500.

Our specific comments are detailed in Appendix A.

Sincerely,

/s/
Charlene MacDonald
President and CEO

Appendix A
FAH Detailed Comments Interoperability Standards and Prior Authorization for Drugs
Proposed Rule Comments

PART II.A-B INTEROPERABILITY STANDARDS FOR APPLICATION PROGRAMMING INTERFACES AND ELECTRONIC PRIOR AUTHORIZATION FOR DRUGS

The proposed rule would require impacted payers to: (1) make available electronic prior authorization (ePA) for drugs; (2) apply many existing interoperability requirements for the PA of non-drug items and services to PA for drugs; (3) report their application programming interface (API) endpoints and related information for the Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and PA APIs to CMS; and (4) require use of certain Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) implementation guides (IGs) that are unexpired as they are adopted by ONC in subpart B of 45 CFR Part 170, beginning on October 1, 2027.

In general, FAH supports the standardization of the prior authorization (PA) process and availability of information between payers, providers, and patients. Automating and expediting these processes can allow providers to devote critical time to providing patient care, reduce administrative burdens for providers, and enable greater alignment across interoperability standards requirements that impact payers, health care providers, health IT developers and other parties. While these proposals are directed at "impacted payers", they also impact providers indirectly and our members have raised several concerns and recommendations for successful and meaningful implementation, discussed below.

Address Medical vs Pharmacy Benefit Ambiguity

As proposed, drugs covered under a medical benefit would be supported through the FHIR PA API, whereas drugs covered under a pharmacy benefit would be supported through National Council for Prescription Drug Programs standards, including SCRIPT, Formulary and Benefit, and Real-Time Prescription Benefit standards. We appreciate CMS's recognition that medical and pharmacy benefit workflows are different and we support use of the FHIR PA API for items and services, including drugs covered under a medical benefit. We also support use of established National Council for Prescription Drug Programs standards for drugs covered under a pharmacy benefit.

The proposal, however, would not provide for uniformity nor standardization across impacted payers as to which drugs would be included under which benefit. We are concerned about the likely resulting variations, depending on payer, in how drugs may be treated (as under a medical or pharmacy benefit). It is essential that providers are able to clearly identify which drugs are covered under which benefit in a timely manner and for electronic health record systems to be able to support the right technology. The primary operational challenge is that some drugs may be covered under either benefit, depending on product, route of administration, site of care, payer policy, and plan design. When the applicable benefit is unclear, a provider may submit the request through the wrong pathway, receive a rejection or request for resubmission, and lose time while the correct route is identified.

To address this, we recommend CMS require impacted payers to publish machine-readable routing logic that identifies the correct ePA pathway for drugs that may be subject to either medical benefit or pharmacy benefit coverage. This routing logic should include benefit classification, applicable plan or product information, payer endpoint, effective dates, and version information. **We also recommend CMS establish a provider safe harbor when a PA request is submitted through a payer-designated endpoint identified through formulary data, real-time prescription benefit information, or published API metadata.** Providers

should not bear operational risk, and patients' care should not be delayed or otherwise negatively impacted, when providers reasonably rely on payer-published information.

Implement a Phased-In Approach for the Prior Authorization API Expansion

CMS proposes to expand use of the PA API and related FHIR IGs, including Health Level Seven (HL7) Da Vinci Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS).

We support CMS's effort to advance FHIR-based PA standards. If implemented well, these standards can reduce manual work, improve transparency, and support faster decisions. However, even though the proposals would not impose requirements *directly* on providers, there are potentially significant indirect impacts on providers that should be acknowledged and mitigated against throughout the implementation process. Of particular note, the proposed requirements represent a significant change in PA workflows and operations. Readiness will vary across payers, health IT vendors, intermediaries, and providers. A nominally compliant API will not reduce burden if payer rules are incomplete, testing environments are unavailable, authentication is unclear, or EHR workflows cannot reliably present coverage requirements to the right clinical or administrative team. EHR systems are expensive and require vendor support for implementation. **To the extent that requirements placed on payer systems necessitate changes and updates to provider systems, time, resources, and support is essential, especially to ensure provider time devoted to patient care is not negatively impacted.**

In addition to the indirect impacts of the impacted payer requirements on providers discussed above, the proposals may impact completion of measures under the electronic prescribing objectives in the Medicare Promoting Interoperability program and the MIPS Promoting Interoperability performance category, affecting eligible hospitals and critical access hospitals as well as MIPS eligible clinicians. Participants in these programs would also be required to meaningfully use certified health IT capable of electronic PA for prescription drugs using the NCPDP SCRIPT standard version 2023011 by January 1, 2028.

For all of these reasons, FAH recommends a phased implementation approach. By the initial compliance date, CMS should require payers to publish coverage requirements, documentation expectations, endpoint metadata, authentication requirements, version information, and testing environments. Full transactional enforcement of CRD, DTR, and PAS workflows should occur only after a defined validation period. CMS should also coordinate with ONC so certified health information technology capabilities and payer obligations align in timing, scope, and technical expectations. This approach would reduce duplicative work, avoid conflicting timelines, and improve the likelihood that ePA functions reliably in production settings.

Preserve Provider Certified Health Information Technology Flexibility

In proposing and implementing policies that are directed at "impacted payers," as discussed above, CMS should not create or imply a provider-side requirement that ePA transactions must originate only from certified electronic health records technology (CEHRT). **FAH strongly urges CMS not to limit provider ePA workflows to certified health information technology. Doing so would create significant operational risk, reduce provider flexibility, and make implementation more difficult.**

Electronic PA workflows do not occur within a single system. A medication order may begin in the electronic health record, move through an electronic prescribing vendor, rely on formulary or real-time benefit information, and then require a separate PA transaction. These workflows may also involve clearinghouses, intermediaries,

centralized enterprise services, or payer connectivity platforms. Requiring all ePA activity to originate from or remain within CEHRT would not reflect how care is delivered or how technology is deployed at scale.

This concern is significant for hospital systems because it could materially affect implementation strategy. A certified health information technology-only approach could prevent providers from using third-party authorization engines, enterprise integration layers, or centrally managed payer connectivity solutions that may be better suited to support complex hospital operations. It also could force duplicative direct connections between individual hospitals, EHR instances, and payers, increasing cost, testing burden, cybersecurity review, and operational complexity without improving patient care.

Therefore, CMS should preserve (and expressly clarify it is preserving) provider flexibility to use certified health information technology, certified modules, electronic prescribing vendors, intermediaries, or other technology partners to support ePA workflows. The controlling requirement should be whether the *transaction* uses the required standards and maintains appropriate data integrity, privacy, security, and auditability, not whether every workflow component is certified EHR technology. **In the final rule, we recommend that CMS clearly state that any finalized payer obligations do not create a provider-side CEHRT usage requirement. In the future, if CMS considers adding drug ePA to provider reporting programs, then CMS should first coordinate with ONC to ensure that certified technology developers support the applicable IGs and that providers retain flexibility to use compliant intermediary or enterprise-level solutions.** This clarification is essential to avoid unnecessary implementation burden, preserve scalable system design, and prevent disruption to existing prescribing and PA workflows.

PART II.C. IMPROVING COMMUNICATIONS AND DECISION TIMEFRAMES FOR PRIOR AUTHORIZATIONS

FAH applauds CMS' continued efforts to address the issue of PA and focus on mitigating the negative impacts the PA process has on patients in accessing needed health care. We agree with the concerns shared by CMS that the PA process creates delays in accessing care and "is a primary source of burden for both providers and payers and can create a health risk for patients if they don't receive medically necessary care in a timely manner."[2] Delays in responding to PA requests for drugs are one example where the PA process continues to significantly impact patient care, particularly by affecting providers' ability to furnish recommended medical treatment, procedures, and medication and increasing provider burden. PA is a burdensome process that diverts limited provider resources away from patient care and may prompt patients to delay or forego needed care, including medications.

We strongly support CMS' proposals to put patient care first by improving decision timeframes for PAs, including for drugs, and improving transparency initiatives around impacted health plans' use of PA. At best, PA processes can provide patients with the financial security that comes from knowing that their care will be covered, but our members have observed that PA 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.

FAH agrees that shortening and standardizing timeframes for PA decisions for drugs and non-drug items and services across impacted payers would improve access to health care and help to mitigate the negative impacts of delays. We continue to believe that transparency is critical for holding health plans accountable for practices that impact patient access to covered benefits (including PA and other utilization management activities) and to allow patients to make informed choices regarding their enrollment and coverage. Therefore, as explained further below, **FAH strongly urges CMS to shorten and standardize, to**

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[2] 91 FR 19899. https://www.federalregister.gov/d/2026-07205/p-115.

the greatest extent possible, PA timeframes across impacted payers, and expand its reporting and disclosure requirements to provide both CMS and consumers with greater insight into impacted payers' use of PA for drugs and non-drug items and services.

We also urge CMS to work with stakeholders and Congress to advance legislation, such as the Medicare Advantage Improvement Act and *Improving Seniors' Timely Access to Care Act*. Specifically, FAH has long advocated for legislation to reform PA and strengthen reporting requirements to protect Medicare Advantage enrollees from delays in care and denials. These goals are consistent with those supported by the proposals set forth in the proposed rule.

Strengthen Denial Transparency and Structured Standardization

CMS proposes to build upon its policy finalized in the 2024 CMS Interoperability and Prior Authorization final rule, which requires impacted payers to provide health care providers with a specific reason for denying a PA request for non-drug items and services. Under this proposal, impacted payers would also be required to provide health care providers with a specific reason for denying a PA request for any drug, regardless of the method used to submit the PA request or communicate the decision.
FAH and its members continue to be strongly supportive of greater transparency into denials of PA requests. We therefore support this proposal as an important step toward clearer communication among payers, providers, and patients. We agree that if a denial is not effectively and timely communicated it could cause a patient to delay or abandon care. It is essential that a provider understands the reason for a denial so that the provider can, as appropriate, effectively address the reason.

We recommend that CMS strengthen this proposal by requiring denial communications to include both structured and narrative information. A narrative denial reason alone will not support scalable operations. Without structured data, providers will continue to rely on manual review, payer-specific interpretation, and inconsistent follow-up workflows. **Each denial should include a structured denial code, a plain-language explanation, the specific missing documentation or unmet criterion, the applicable coverage policy or medical necessity requirement, the appeal or resubmission pathway, and whether alternative therapies or services would meet coverage criteria. It is essential that a "specific reason" for a denial clearly and effectively communicates actionable information that the provider is able to use to take appropriate actions on behalf of the patient.**

Further, FAH urges CMS to clarify that the impacted payer is obligated to provide *each* specific reason for the denial. When there is more than one reason for a denial, providing each reason is critically important so that the provider is able to evaluate whether it would be appropriate to resubmit with additional information, appeal the determination, or take other action. It is imperative for the provider to receive the complete menu of reasons for the denial, rather than receiving reasons piecemeal or alternative reasons in a progression of PA request attempts. A process that allows for the piecemeal progression of reasons is unnecessarily burdensome and inappropriately prolongs the PA process to the detriment of patients. Requiring that each reason for a denial be included would give the provider and patient the opportunity to fully and efficiently evaluate appropriate next steps.

While our observations and recommendations are directed to the proposal to include a specific reason for a denial of PAs for drugs, they are also applicable to the current requirement for impacted payers to provide a specific reason for a denial of PAs for non-drug items and services and we urge the agency to consider in future rulemaking changes to apply our recommendations for PA requests and responses for non-drug items and services as well. We also note that our members continue to have concerns with payers' inappropriate downcoding and PA decisions. Inappropriate downcoding effectively denies the treatment

course that is recommended by the provider. We urge that in CMS' future considerations, steps are taken to adequately provide oversight, transparency, and accountability on payers' effective denial of recommended and needed care through the practice of down-coding.

Prior Authorization Decision Timeframes: Align Payer Notification Requirements and Account for Acute Care Operational Impact

CMS proposes several policies regarding PA timeframes. CMS proposes that qualified health plan (QHP) issuers on the Federally Facilitated Exchanges (FFE) notify providers of PA decisions for non-drug items and services by not later than 7 days for standard requests and 72 hours for expedited requests, while retaining existing patient notification requirements (which specify 15 days for standard requests and 72 hours for expedited requests). CMS also proposes that, beginning October 1, 2027, these QHP issuers notify requesting providers of PA drug decisions as quickly as the patient's condition requires, but no later than 72 hours for standard requests and 24 hours for expedited requests. In addition, CMS proposes that for Medicaid PA timeframes for drugs that are incident to a non-drug service (and thus not included as a covered outpatient drug) PA timeframes should align with those applicable to the non-drug service timeframes (i.e., 7 days for standard requests and 72 hours for expedited requests). Lastly, the agency proposes to align PA decision timeframes for drugs under CHIP FFS programs with the timeframes applied under Medicaid FFS by requiring notification of such decisions be made within 24 hours.

FAH supports shortening timeframes by which impacted payers must respond to PA requests and to the greatest extent possible, aligning those timeframes across impacted payers. We encourage CMS to continue its efforts in achieving these goals and as discussed below, we have several recommendations to strengthen the proposals in furtherance of these goals.

We specifically applaud the agency's proposal to improve transparency and communication of PA decisions with providers by requiring QHP issuers on the FFE to notify providers of PA decisions for non-drug items and services. Receiving clear and timely communications is essential for providers to be able to care for their patients. However, FAH continues to have significant concerns that the proposed timeframes, 72 hours for expedited requests and 7 days for standard requests, 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. **We urge CMS to account for the acute care impact of unnecessarily lengthy PA response timeframes. In hospitals, PA decisions can affect time-sensitive transitions, including discharge medications, post-acute services, hospital outpatient infusion scheduling, emergency department follow-up, and specialty drug administration.**

We also urge the agency to align the timeframes for patient notifications with the timeframes that would be applied for provider notifications. Our members report confusion when their patients receive PA denials after the denial has been successfully overturned—and sometimes even after services have been rendered. Aligning provider and patient notice timing would reduce patient confusion, avoid duplicative calls, and support safer transitions of care. Provider and patient notices should include consistent decision information, including whether the request was approved, denied, or pending for missing information, and should clearly state the next steps.

We support CMS' proposal to align the timeframe under CHIP FFS programs with the timeframe under Medicaid FFS programs for notifying providers of PA determinations for drugs by requiring such notification be provided within 24 hours. However, given the benefit of advances in technology, we believe PA determinations could be provided during the same business-day and we urge the agency to use this timeframe as the model to apply consistently across impacted payers for both non-drug items and services as well as drugs, to the extent permitted under statute. **Accordingly, FAH recommends that both providers and patients receive**

notification of PA determinations on the same business day whenever possible and no later than 24 hours after a determination is made for either drug or non-drug requests. The extensive variations in PA timeframes based on payer type exacerbates an already complicated and time-consuming PA process. Consistent, standardized timeframes across impacted payers would be an enormous improvement to this process. Navigating the differing requirements based on type of impacted payer is an unnecessary impediment in the process of seeking PA. Therefore, to the extent permitted under statute, we implore the agency to consistently align PA response timeframes and provide for concurrent notifications to providers and patients during the same business day and alternatively by not more than 24 hours after a PA request, regardless of the type of impacted payer.

Additionally, we remain concerned with the lack of an efficient process for addressing impacted payers' failure to comply with existing and the proposed PA timeframes. FAH supports a policy under which a payer's failure to meet the PA timeframes would result in a deemed authorization that may not be denied, reviewed, or audited for medical necessity or coverage. Such an approach would establish appropriate and effective incentives for impacted payers to more consistently track and process PA requests in a timely and responsive manner and minimize the negative impact of payers' non-compliance with PA requirements on patients receiving recommended and needed health care treatments and medications.

Reporting Prior Authorization Measures

In the 2024 CMS Interoperability and Prior Authorization final rule, CMS finalized requirements for impacted payers to publicly report PA measures aggregated for all non-drug items and services. CMS is now proposing changes to these requirements, including to: require a numeric count in addition to the percentage of PAs for the existing measure; require Medicaid managed care plans and CHIP managed care entities to report these measures at the program level in addition to the currently required plan level; add measures relating to requests denied after appeal and requests for which the timeframe for review was extended and the request denied to complement the existing measures related to approved requests; and add measures for expedited requests to complement similar existing measures applicable to standard requests. In addition, CMS proposes, beginning in 2028, to require impacted payers to annually report measures about PA for drugs.

FAH applauds CMS' efforts to strengthen transparency, oversight, and impacted payer accountability regarding PA practices. **We support the proposed changes to the existing reporting requirements and measures for non-drug items and services and the proposal to require impacted payers to also report measures on PA for drugs.** However, we encourage CMS to further require disaggregation of measures 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. **Specifically, we urge CMS to require reporting on PA measures for *each* category of items and services (*e.g.*, inpatient or outpatient 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 PA measures across items and services will result in high volume PA 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 PA requests for high-intensity and time-critical items and services, including post-acute care services such as inpatient rehabilitation, at disproportionately high rates.** Without item- and service-level reporting, it will be impossible for CMS and the public to understand whether an impacted payer's PA practices are disproportionately affecting enrollees with specific needs and to hold impacted payers accountable for excessive denials and delays in responding to PA requests, including for post-acute care services.

Prior Authorization Enforcement and Accountability

While FAH supports the proposals for improvements to the PA process, with the suggested refinements described above, we strongly encourage CMS to prioritize enforcement and impacted payer accountability with respect to the PA requirements being proposed for drugs and that have already been finalized for non-drug services. Shorter and consistent PA timeframes and enhanced transparency around PA processes and practices are essential steps, but those steps are not sufficient without effective enforcement of the requirements and enhancing payer accountability.

Although providers and patients can challenge or appeal an impacted payer's inappropriate denial of or failure to act on a PA request, pursuant to contract, regulation, or both, the availability of internal and external review processes and further appeals is insufficient to promote PA 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 PA 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 PA requests, as observed by the OIG in its April 2022 report.[3] Against this backdrop, FAH is concerned that such practices will not be sufficiently checked by transparency around PA metrics and thus urges CMS to use its enforcement authority to tackle inappropriate utilization management practices head-on.

To that end, FAH recommends that CMS undertake rulemaking to expand its oversight and enforcement mechanisms with respect to PA practices. 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 and drugs for which PAs are routinely delayed, denied, and/or overturned, disaggregated by payer type.
- Engaging in routine audits of impacted payers to assess compliance with PA requirements, including the timeliness of decisions and accuracy and completeness of public reporting of PA data.
- Imposing sanctions for the inappropriate use of PA processes to deny or delay coverage of items, services, or drugs.
- Ensuring inclusion of quality measures in the various quality star rating programs (*e.g.*, for MA organizations and QHP issuers) reflecting the timeliness of PA decisions and the rates at which PA denials are overturned for each level of the appeals process.

PART II.E REPORTING PAYER API ENDPOINTS AND ASSOCIATED INFORMATION FOR CMS TO PUBLISH

CMS proposes to require impacted payers to report to the agency their Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization API endpoints and related information. Impacted payers would be required to initially report their API endpoints no later than 60 days after the effective date of the final rule; in future years, new impacted payers would be required to report this information no later than 60 days before they begin covering patients under the applicable CMS program.

FAH supports CMS's proposal to require payer endpoint publication. Reliable endpoint discovery is essential to scaling interoperability and reducing payer-by-payer administrative complexity. However, without

[3] 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.

centralized and accurate endpoint information, providers and vendors must continue to identify payer URLs, registration processes, capability statements, and support contacts one payer at a time.

We therefore recommend that CMS establish or designate a standardized, FHIR-enabled national registry for payer API endpoints. The registry should include endpoint URLs, capability statements, authorization and authentication requirements, version metadata, effective dates, test environments, maintenance information, and technical support contacts. CMS should also allow an initial stabilization period before enforcement so payers, providers, and vendors can validate registry data, correct errors, and confirm that published endpoints work in production workflows.

PART II.F REMOVING DRUG FORMULARY INFORMATION FROM THE PROVIDER ACCESS AND PAYER-TO-PAYER APIS

In section II.F.3, CMS seeks comment on its proposal to remove drug formulary information as data that must be made available via the Provider Access and Payer-to-Payer APIs for MAOs, State Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities.

Throughout the preamble to the proposed rule, CMS refers to the desirability of centralized sources of information and assisting providers and patients to identify and connect to payer APIs. The preamble also highlights the burden imposed on all parties in locating information across different websites or other sources of information. Providers are regularly asked by patients to help them navigate plan formularies for many reasons, including determining whether the provider's recommended medication is included in the formulary and, if it is on the formulary, whether there are any additional documentation requirements for the medication and in the case of MAOs any cost-sharing implications.

FAH believes that if it is technologically feasible to include complete drug formulary information in the Provider Access API, CMS should require those APIs to include that information in order to reduce burden on providers and their patients and to facilitate clinical decision making for patients and providers.

PART II.H MODIFICATIONS TO HIPAA STANDARDS RELATED TO PRIOR AUTHORIZATION

HHS also is proposing to adopt the HL7 FHIR standard and certain associated specifications and IGs as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards for dental, professional, and institutional "referral certification and authorization" transactions and "eligibility for a health plan" transactions associated with PA. The FHIR standard would replace the present X12N 278 standard for transmissions related to PA. The proposed compliance date would be 24 months after the effective date of the final rule in the Federal Register, except for small health plans beginning 36 months after the effective date of the final rule in the Federal Register. Unlike CMS' proposals discussed earlier that would only apply to "impacted payers," the HHS proposals in this section would apply to all HIPAA covered entities, including hospitals.

Given currently available technologies, FAH supports the continued development of the FHIR framework to advance these goals. However, while FHIR technology holds great promise if implemented correctly and is now more prevalent among covered entities than several years ago, it still remains largely untested and many covered entities have multiple legacy systems that do not currently support FHIR. **Given the limited operational experience and use cases with this technology, therefore, FAH urges HHS and CMS to engage in ongoing review and oversight of the FHIR framework to ensure it provides the flexibility needed to support these APIs and achieve their purpose. Specifically, we urge HHS to ensure the technology is sufficiently developed, adopted and tested on a wide-scale basis all to ensure that**

implementation can be successful across covered entities. Requiring use of a FHIR standard too soon will not achieve its purpose and covered entities will need to augment that standard for legacy systems

PART III. REQUESTS FOR INFORMATION

Request for Information (RFI) on Electronic Event Notifications for Value-Based Care and Care Coordination

In this RFI, CMS asks whether certain standards or requirements for patient matching could improve electronic event notifications. CMS also asks about processes for attribution and patient matching between hospitals, accountable care organizations, post-acute care facilities, payers, long-term care facilities, social service providers, emergency medical services, behavioral health providers, and other entities.

FAH supports national patient matching standards that improve interoperability and patient safety through standardized demographic data and better matching accuracy, while cautioning against overly prescriptive or burdensome mandates on hospitals and EHR workflows. These standards should be industry-led, accurate, flexible, feasible, scalable, coordinated with vendors and not create undue provider burden.

FAH supports policies that improve accurate patient identification and matching across systems to reduce medical errors, duplicative testing, and fragmented care. Stronger matching standards not only enable better care coordination and support patient safety, but also are essential in protecting patient privacy, data security, and avoiding patient harm from data mismatches. Patient matching is foundational for effective health information exchange. **Therefore, we recommend that CMS treat patient matching as a stand-alone infrastructure issue across the interoperability ecosystem, not only as a technical consideration for electronic event notifications.** Electronic PA, bidirectional exchange, patient access, payer-provider exchange, public health reporting, and care coordination all depend on the ability to accurately identify and match patients across systems.

In formulating any policies regarding patient matching, FAH urges CMS to avoid prescriptive requirements that are operationally burdensome or difficult to implement across different EHR systems and workflows. One-size-fits all mandates will not provide the flexibility needed to take into account the diverse landscape of health information networks and exchanges, EHR platforms, and exchange participants.

Patient matching approaches remain inconsistent across networks, EHR platforms, health information exchanges, payers, and other exchange participants. Variation in enterprise master patient index practices, demographic matching algorithms, identity proofing, and required data attributes creates operational complexity and increases the risk of incomplete or inaccurate exchange. In the context of PA, inaccurate matching can create missing documentation, inappropriate disclosures, delayed decisions, or requests tied to the wrong patient record.

We recommend that CMS work with ONC and other federal partners to develop more specific national guidance for patient matching across the interoperability ecosystem. This guidance should address *minimum* demographic data standards, consistent matching expectations, enterprise master patient index capabilities, identity proofing approaches, and governance expectations for health information networks and exchange participants. Improving patient matching will strengthen the foundation for CMS's broader interoperability priorities and reduce downstream implementation barriers for hospitals, payers, health information technology developers, and patients.

Request for Information on Increasing Health Care Resiliency

CMS seeks input on the most significant cybersecurity challenges facing health care organizations, effective practices for preventing and recovering from cyberattacks, the role of CMS-related requirements, and how interoperability can be advanced in a manner that enhances security. CMS notes that the health care system's reliance on digital infrastructure creates vulnerabilities that can be exploited by cybercriminals, and that recent breaches and ransomware attacks have disrupted care operations, threatened patient safety and privacy, and undermined progress toward digital health transformation.

FAH appreciates CMS's continued focus on strengthening cybersecurity and resiliency across the health care sector. Cybersecurity is now inseparable from care delivery. Hospitals must protect sensitive patient data while maintaining continuous access to electronic health records, clinical applications, medical devices, imaging, pharmacy, revenue cycle, and other systems necessary for safe and timely care. It also should be recognized that hospitals and health systems spend and apply a significant and ever-increasing amount of resources, financial and otherwise, to strengthen their cybersecurity defenses to protect patient safety and electronic protected health information, against increasingly sophisticated cyberattacks, many by state actors aimed at the health care sector and critical infrastructure of the United States. **To effectively achieve the goal of mitigating cyber threats, health care entities must not be overly burdened with documentation and must have the capacity and support to invest resources in modernizing information systems.** To that end, we appreciate the focus of the June 2 AI Executive Order, *Promoting Advanced Artificial Intelligence Innovation And Security,* is to work collaboratively with the private sector and not stifle innovation with overly burdensome regulation.

Health care organizations face an increasingly complex threat environment, including ransomware, third-party vendor compromise, credential theft, phishing, exploitation of legacy systems, supply chain vulnerabilities, and attacks that disrupt clinical and operational systems. These risks are heightened by the sector's dependence on interconnected vendors, payers, clearinghouses, medical device manufacturers, and other technology partners. The expanding use of artificial intelligence also introduces new security and governance considerations, including the need for more frequent patching, monitoring, access controls, data protection, and vendor oversight. Health care organizations are also seeing emerging workforce-related cyber risks, including candidate and employee impersonation schemes that can be difficult to detect through traditional onboarding processes. CMS should recognize that cyber resiliency now extends beyond technical controls and includes workforce identity verification, vendor access governance, and operational readiness.

FAH believes maintaining flexibility and scalability is necessary for a security framework that will apply to health care providers ranging from large health systems to small solo practitioners. In addition, recognizing the considerable complexity, nuances, and costs of implementing cyber protections in the health care industry, **FAH encourages CMS to consider a risk-based approach to ensure that monitoring of critical systems allows regulated entities to focus on mitigating the highest risks in a timely manner as opposed to spreading the entity's resources more thinly across lower risk systems on a real-time basis.**

Small and rural providers face cyber resiliency challenges more acutely due to limited capital, older infrastructure, fewer cybersecurity personnel, and reduced access to specialized expertise. CMS should account for these differences by supporting incremental, scalable, and flexible risk-based expectations that improve resilience without creating unrealistic or unfunded compliance obligations. FAH supports approaches that would allow regulated entities of all sizes and levels of sophistication to build their cybersecurity resilience in a consistent and incremental manner based upon their own circumstances, resources, maturity, and risk level.

We support CMS encouraging cybersecurity practices that strengthen preparedness, response, and recovery, including isolated and immutable backups, recovery environments separate from production systems, redundant infrastructure for critical systems, tested incident response plans, tabletop exercises, vulnerability management, network segmentation, identity and access management, access logging, third-party risk management, and recovery testing. Multi-factor authentication is particularly important given the prevalence of credential compromise, especially across web-based and third-party systems.

CMS should align cybersecurity expectations with HIPAA, HHS Cybersecurity Performance Goals, NIST guidance, ONC certification policy, and other federal frameworks. New requirements should avoid duplicative attestations, provide reasonable implementation timelines, and recognize that regulatory compliance does not always equate to operational resilience.

Interoperability and cybersecurity must advance together. As CMS expands reliance on APIs, payer-provider exchange, PA workflows, and trusted exchange relationships, each new connection must be supported by clear expectations for identity, authentication, authorization, monitoring, audit logging, and accountability.

CMS should promote security-by-design interoperability policies, including least-privilege access, secure APIs, standardized authentication, encryption, segmentation, vulnerability disclosure, coordinated patching, third-party incident reporting, and clear incident response responsibilities. A secure interoperability framework should establish shared accountability across providers, payers, vendors, intermediaries, medical device manufacturers, clearinghouses, and other participants in the health care technology ecosystem. Responsibility for cybersecurity should not rest solely with providers when risks arise from interconnected third-party systems.

We recommend that CMS avoid creating duplicative cybersecurity or EHR safety attestation obligations. The SAFER Guides assessment is resource-intensive and requires coordination across clinical, operational, technical, privacy, security, and EHR governance teams. This level of effort can divert resources from direct patient care, cybersecurity, system optimization, and other high-priority interoperability activities. In addition, several recommended practices remain subject to interpretation, which may result in inconsistent review and uncertainty regarding expectations. We recommend that CMS transition the SAFER Guides measure to an optional measure beginning in CY 2027. If CMS continues to require the measure, CMS should reassess whether annual mandatory attestation is necessary given overlap with existing program requirements and certified EHR technology safeguards; recognize alternative EHR safety demonstrations, including participation in recognized EHR safety, cybersecurity, or health IT governance programs; and consider a shared responsibility model that recognizes the role of certified health IT developers in EHR safety, system configuration, and technical capabilities.