Charles N. Kahn III
President and CEO

January 4, 2021

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

> ***Re: Medicaid Program; Patient Protection and Affordable Care Act; Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information for Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-facilitated Exchanges; Health Information Technology Standards and Implementation Specifications [CMS-9123-P]***

Dear Administrator Verma:

The Federation of American Hospitals (FAH) is the national representative for over 1,000 leading tax-paying 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 America. Our members include teaching and non-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 comment to the Centers for Medicare & Medicaid Services (CMS) on the above Notice of Proposed Rulemaking (Proposed Rule) published in the Federal Register (85 Fed. Reg. 82586) on December 18, 2020.

General Comments

The FAH and our members strongly support the use of health information technology (health IT) to improve the health care delivery system through improved continuity of care and

empowering patients and their caregivers with the information and tools they need to become engaged as active participants in their health care. We believe these priorities can be achieved in a manner that reduces the regulatory burden placed on health care providers and are committed to working in concert with CMS, the Office of the National Coordinator for Health IT (ONC), and the Department of Health and Human Services (HHS) to realize these goals.

The FAH agrees with CMS that prior authorization processes are an appropriate area for targeting better electronic data exchange. While aimed at reducing unnecessary medical care, prior authorization also poses a potential barrier to timely necessary medical services and, as noted in the Proposed Rule, the operational procedures are often burdensome for providers. For hospital inpatients, delays in prior authorization can result in longer hospital stays that drive up costs as well as inconvenience patients and caregivers.

The FAH has previously commented[1] regarding our members' concerns with delays and inconsistencies across plans and payers, including lack of transparency and clarity regarding the guidelines plans use to evaluate prior authorization requests, delays in plans approving requests, medical reviewers not having the relevant clinical/patient care and professional experience with the benefit or service they are reviewing, varying authorization and documentation rules across payers and across plans within the same payer, lack of ability to rely on prior authorization approvals, and onerous and confusing appeals processes.

Making prior authorization processes more efficient is an important first step toward helping to minimize detrimental delays in patient care and reduce administrative burden on providers. **Although the FAH is supportive of many of the proposals included in the Proposed Rule, we are concerned that the abbreviated comment period does not provide a meaningful opportunity to comment on the detailed and technical proposals presented and strongly urge CMS and ONC to extend or reopen the comment period.** The current January 4, 2021 deadline for comments leaves stakeholders with only a 24-day comment period that spans two federal holidays and eight weekend days, leaving a comment period of only 14 business days. This extraordinarily short comment period is made all the more problematic by the complexity and length of the Proposed Rule, which spans 97 pages of the Federal Register and covers a wide range of topics, some of which are highly technical in nature. In light of these constraints, the FAH has been unable to provide CMS with comments that reach the level of technical detail that is warranted by the Proposed Rule. There is no practical or legal reason a 60-day comment period consistent with Executive Order 13563 and 5 U.S.C. § 553 is not possible, and we encourage CMS and ONC to extend the comment period by at least 60 days or to reopen the comment period so that stakeholders will have a meaningful opportunity to comment on CMS's and ONC's proposals, particularly with respect to the technical details set forth in the Proposed Rule. High-level comments on key topics follow.

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[1] FAH Comment Letter re: Center for Program Integrity Request for Information on the Future of Program Integrity, November 20, 2019, see pages 5-7: https://www.fah.org/fah-ee2-uploads/website/documents/112019_FAH_Program_Integrity_RFI_-_FINAL.pdf.

<u>Affected Payers and Services</u>

The FAH urges CMS to include Medicare Advantage (MA) organizations in the proposals to improve payer-provider electronic data exchange, with a particular focus on prior authorization. In the preamble to the Proposed Rule, CMS and ONC assert, without explanation, that they "currently do not believe it is necessary to apply these policies to Medicare Advantage organizations." The FAH disagrees and urges CMS to apply these policies broadly and consistently. CMS's authority to regulate various types of health plans – including Medicaid and CHIP fee-for-service (FFS), Medicaid and CHIP managed care, and qualified health plan (QHP) issuers on the Federally-Facilitated-Exchanges – puts CMS "in a unique position to be able to align policies across these programs to the benefit of patients across the nation." Adding MA organizations to this list would only improve the patient experience further, and the FAH strongly urges CMS to apply these policies to MA organizations. In particular, many of the proposals set forth in the Proposed Rule are designed to improve the experience of patients who "churn" across health plan types and applying the proposed policies to MA plans would serve the interests of dually eligible beneficiaries. Moreover, MA plans were included in the May 2020 final rule on Patient Access and Interoperability, which required payers to establish a patient access Application Programming Interface (API); they should not be excluded from the next steps. For FAH members and other providers to garner the most benefit from any investments in updating health IT systems and related training that CMS expects would be needed to interact with the Provider API and the two prior authorization APIs as proposed, they should apply to as many payers as possible.

In addition, the FAH urges CMS to expand these policies to prescription drugs and covered outpatient drugs to address the entire prior authorization landscape.

<u>Prior Authorization APIs</u>

The proposals to require payers to establish APIs that allow electronic data exchange for prior authorization requests could be a useful start at improving the prior authorization process. The proposed Document Requirement Lookup Service (DRLS) API would allow providers to query the prior authorization requirements for specific items and services and identify documentation requirements. The Prior Authorization Support (PAS) API would support electronic exchange between providers and payers with respect to prior authorization requests and responses. We appreciate that these APIs are intended to make it easier for providers to identify payer requirements for prior authorization, electronically submit prior authorization requests, and receive payer decisions within their health IT systems. **The proposal does not include any requirements for electronic health records (EHRs) for interaction with these APIs. In further developing this policy, CMS should ensure that there is sufficient standardization in the payer data exchange to avoid inadvertent inconsistencies in advancing electronic prior authorization processes.** To the extent that CMS is expecting providers to invest significant resources in their EHRs or practice management software to interact with these proposed APIs, the policy will not have the intended result.

<u>Information on Denials</u>

The FAH strongly supports the proposal to improve prior authorization processes by requiring that payers specify a reason for denial. When a denial is made with no explanation, patients must wait while providers pursue appeals without knowing how to present the request to the payer's satisfaction. The final rule should clarify the *specific* information that payers would provide on the reasons for denial so that this information is complete, clear to providers and patients, and consistently available across payers. Greater specificity in the reason for denial, including meaningful explanations and rationales for any denials – as opposed to simply citing a coverage regulation – is key and will help avoid arbitrary denials and allow patients and providers to learn more about the prior authorization process to avoid unnecessary requests and appeals.

<u>Transparency</u>

Impacted payers would be required to publicly report certain prior authorization metrics on their websites at least once a year, including a list of items and services that require prior authorization and rates of approvals, denials, approvals after appeal, extensions of review time, approvals of expedited review, and median and average elapsed time between a standard request and decision. All this information would be aggregated separately for items and for services.

The FAH supports public reporting of prior authorization metrics by payers and believes such information should be reported quarterly. This information would help providers understand each payer's operations around prior authorization, and public reporting could encourage payers to make timely decisions or better target the items and services for which prior authorization is required. This information may also be of interest to consumers as they consider their choice of QHPs or managed care plans under Medicaid or CHIP.

<u>Patient Access API</u>

The FAH supports improved transparency for patients by adding information on active and pending prior authorization requests, documentation, and forms, to the Provider Access API that was adopted in the May 2020 Patient Access final rule. The information would need to be available no later than one business day after the prior authorization request is made, or its status is changed. We agree with CMS that it would be helpful to providers to make available to patients information about the prior authorization process and status of requests made on their behalf. The FAH also believes it would be helpful to both providers and patients to require plans to include information about previously approved or denied prior authorization requests, as well as information about prior authorizations related to prescription drugs and covered outpatient drugs.

The FAH also strongly encourages CMS to reconsider the requirement that laboratory results be made available to patients immediately. Certain lab results can carry extremely upsetting information, like the results of biopsies. Many such laboratory results need to be properly contextualized for patients to understand the information and would be better

delivered by a health care professional either in person or via a phone call. We urge CMS to consider delaying the posting of such results to give providers a chance to communicate directly with their patients.

We support the requirement that plans request a privacy policy attestation from third-party applications that will access the API but recognize the existence of privacy policies alone will not do enough to ensure that patient information is not misused by entities outside of HIPAA coverage. Misuse of health information by companies offering third-party applications could negatively impact the trust patients place in their caregivers. **As such, CMS and ONC should work with other agencies to undertake a joint education campaign for patients as well as support an independent, industry-backed "vetting" process for third-party applications to ensure they are: meeting all relevant security standards; using data appropriately and in line with consumer expectations; and clinically sound (for those applications that offer medical advice).**

Time Limits for Prior Authorization Decisions

The FAH supports placing limits on the time payers take to act on prior authorization requests. Delayed decisions are one of the ways in which prior authorization disrupts patient care. Under the rule, Medicaid and CHIP programs and managed care plans would be required to process requests no later than 72 hours following initiation for expedited requests (already the requirement for Medicaid and CHIP managed care) and no later than seven days for requests involving non-urgent items and services. **We strongly encourage CMS to shorten these proposed timelines – and build towards automation of prior authorization processes, to the extent possible – in order to limit the negative effects of prior authorization on patient access to care and provider efficiency.**

Provider API and Payer-to-Payer APIs

The FAH supports the proposal for payers to establish a Provider Access API that would allow providers to access the information included in the Patient Access API, including claims, encounters, clinical data, and information on the status of prior authorization requests. The proposal involves enabling requests on individual and multiple patients using specifications for bulk data exchange. We agree that having electronic access to this information retained by payers could improve a provider's understanding of the patient's health and may reduce the need for patients to recall information for medical history forms, all of which could help improve the efficiency and effectiveness of patient care. However, in light of the potential cost and training requirements for providers to pursue health IT system changes to access this information, we again urge CMS to include MA organizations in any steps to build on the Patient Access API and encourage electronic exchange of information between payers and providers.

If a provider accesses information on a patient through a Provider API, it would be beneficial to have as much patient history available as possible. It may also be beneficial to make new payers aware of active, pending, and previously approved prior authorization requests at the patient's previous payer. For this reason, **we support the proposal to require payers to share**

information with patient approval through a Payer-to-Payer API. The proposal would involve payers (Medicaid, CHIP, and QHPs) among which there is significant churning due to shifts in patient income and program eligibility. Keeping current information on a patient moving between these programs would be in the best interest of the patient and help their providers furnish efficient and effective care.

CMS seeks comment on an alternative under which payers would be required to honor a previous payer's active prior authorization decisions for a period of time (e.g., 30, 45, or 60 days) after a new patient is enrolled. **The FAH urges CMS to require payers to accept any prior authorization approval made by the patient's previous payer for at least 60 days after enrollment.** This would support continuity of care, avoid potentially harmful delays in care, and reduce provider burden. Other approaches that reduce duplicate prior authorizations should also be considered. These might include approaches that limit the need for repeated prior authorizations for items and services for chronic conditions.

Rather than the proposed patient opt-in, which puts the burden on patients to actively allow data exchange between their providers and their payer, CMS should consider allowing this data exchange to occur automatically absent specific patient consent. Because the transaction would occur between covered entities, such exchanges are permitted under the HIPAA privacy rules. Allowing this information exchange without requiring patient approval would maximize the information available to providers, and an opportunity for patient opt-out could be provided to allow patients to preclude a payer from sharing their personal health information with any provider. The Proposed Rule notes that there are multiple ways for payers to attribute patients to providers for purposes of enabling payer-to-provider data sharing via the Provider Access API.

To facilitate use of the Provider Access API, the FAH supports the proposal to require payers to provide educational resources for providers on how to request access to patient data though the Provider Access API for individual patients and bulk data requests. The information would need to be provided on the payer's website and through other mechanisms by which the payer normally communicates with providers. The resources would need to be in non-technical, simple, and easy-to-understand language.

Request for Comment on Prohibiting Post-Service Claim Denials for Items and Services

We are encouraged that CMS is looking into the issue of inappropriate claims denials following the granting of a prior authorization request. Patients and providers should not be financially penalized when they both followed the payer's prior authorization policies. **The FAH strongly urges CMS to prohibit payers from making post-service claim denials for services granted prior authorization.**

Request for Comment on "Gold-Carding" Programs for Prior Authorization

The FAH encourages CMS to pursue its interest in "gold-carding" or similar programs under which payers relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance. We agree that better

targeting of prior authorization by payers could facilitate more efficient and prompt delivery of health care services to beneficiaries. Requiring "gold-carding" programs or rewarding payers that establish them through the star ratings should be strongly considered as one component to reducing the unnecessary burden associated with prior authorization.

Request for Comment on Electronic Prior Authorization for Medicare and Medicaid-Participating Providers and Suppliers

CMS is interested in ways to increase provider use of electronic prior authorization. The FAH supports this goal and believes that while providers should be given opportunities and incentives to use electronic prior authorization, they should not be required to do so. **In particular, the FAH opposes the use of mechanisms like the Medicare and Medicaid Conditions of Participation (CoPs) to encourage greater use of electronic data exchange for prior authorization or other purposes.** CoPs should be limited to the fundamental requirements to ensure safe, reasonable, and necessary care for patients while protecting beneficiaries and tax dollars. Many providers have competing needs for limited resources and using the CoPs to promote certain policies over others may have unintended effects on patient care. Moreover, exclusion from the Medicare and Medicaid programs would not be a reasonable enforcement tool for electronic prior authorization requirements.

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The FAH appreciates the opportunity to comment on the Proposed Rule. If you have any questions, please contact me or a member of my staff at 202-624-1534.

Sincerely,