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AAHKS AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

MEMORANDUM

To: AAHKS

From: Epstein Becker & Green, P.C.

Date: January 22, 2024

Re: **"*Advancing Interoperability and Improving Prior Authorization Processes*"- Final Rule Summary**

On January 17, 2024, the Centers for Medicare & Medicaid Services ("CMS") issued its *Advancing Interoperability and Improving Prior Authorization Processes* final rule (the "Final Rule")[1] to address certain operational and technical aspects of prior authorization[2] for "Impacted Payers," including Medicare Advantage ("MA") plans, Medicaid managed care ("MMC") plans, state Medicaid and Children's Health Insurance Program ("CHIP"), Fee-for-Service ("FFS") programs, CHIP managed care plans, and Qualified Health Plans ("QHPs") available on the Federally Facilitated Exchanges ("FFEs").

Most relevant to AAHKS members, CMS finalized the following key provisions:

- Impacted Payers (except QHPs) must respond to prior authorization requests within 72 hours of expedited requests and 7 calendar days of standard requests;
- Impacted Payers must provide a specific reason for denied prior authorization decisions;
- Impacted Payers must annually publicly report certain prior authorization metrics;
- Impacted Payers must implement and maintain a Prior Authorization Application Programming Interface ("API") to enable automation of certain processes for providers and to facilitate the exchange of prior authorization requests and decisions from provider electronic health records and practice management systems;
- Impacted Payers must satisfy certain requirements for Patient Access API, Provider Access API, and Payer-to-Payer API.
- CMS added a new "Electronic Prior Authorization" measure to the Health Information Exchange objective for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

[1] Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, etc. on the Federally-Facilitated Exchanges, etc., (expected Feb. 8, 2024), https://www.federalregister.gov/public-inspection/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability.

[2] The changes to prior authorization process in the Final Rule do not apply to drugs.

AAHKS' Recent Advocacy Activity Addressing Prior Authorization

The Final Rule addresses key issues AAHKS highlighted in its advocacy efforts addressing prior authorization regulatory activity over the past few years. In March 2022, AAHKS used the comment period of the *Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria Request for Information*[3] to highlight AAHKS' 2022 prior authorization member survey results concerning technical components of electronic prior authorization, operational burdens of payer prior authorization practices, and the clinical and coverage criteria MA plans use for prior authorization. In March 2023, AAHKS provided comments to CMS on the proposed rule and strongly endorsed many of the provisions. AAHKS also suggested to CMS how it could strengthen some of the proposed new requirements to better achieve the rule's intended results.

Notably, the Final Rule corresponds with the operational and technical components of prior authorization while CMS' *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs* (the "MA Technical Final Rule") issued on April 12, 2023, addressed the clinical and coverage criteria used by MA plans.[4] That rule requires the following of MA plans, effective January 1, 2024:

- Once an enrollee is granted prior authorization approval, that authorization remains valid for the full course of treatment;
- Prior authorization policies can only be used to confirm the presence of diagnoses or other clinical criteria and/or ensure that an item or service is medically necessary;
- Plans must provide a minimum 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan;
- To ensure prior auth is being used appropriately, all MA plans must establish a Utilization Management Committee to review policies annually and ensure consistency with Traditional FFS Medicare's national and local coverage decisions and guidelines.

[3] Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria, 87 Fed. Reg. 3475 (Jan. 24, 2022), https://www.federalregister.gov/documents/2022/01/24/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and.

[4] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 88 Fed. Reg. 22120 (April 12, 2023), https://www.federalregister.gov/documents/2023/04/12/2023-07115/medicare-program-contract-year-2024-policy-and-technical-changes-to-the-medicare-advantage-program.

Provisions of the Final Rule

1. **Changes to Prior Authorization Processes in the Final Rule**

    a. **Starting in 2026, Impacted Payers (Except QHPs) Must Send Prior Authorization Decisions Within 72 Hours of Expedited Requests and 7 Calendar Days of Standard Requests.**

Starting in 2026, Impacted Payers (except QHPs) must notify providers and patients of prior authorization decisions as expeditiously as a patient's health condition requires, but no later than 7 calendar days for standard requests, and no later than 72 hours for expedited requests, unless a shorter minimum timeframe is established under applicable state law. CMS declined to create new definitions for the terms "standard" and "expedited," citing that the existing regulatory definitions applicable to the particular Impacted Payer still apply.

    b. **Starting in 2026, Payers Must Provide a Specific Reason for Denied Prior Authorization Decisions.**

Starting in 2026, Impacted Payers must provide a specific reason for denied prior authorization decisions, regardless of the method used to send the prior authorization request, such as through electronic portals, telephone calls, email, standard transactions, or other means. A denial must be sufficiently specific to enable a provider to understand why a prior authorization has been denied and what follow-up actions must be taken to obtain coverage – including whether to appeal, submit additional documentation, or identify alternative treatment options.

CMS stated that the new requirements supplement, and do not alter, existing prior authorization requirements applicable to the respective Impacted Payers and that existing requirements applicable to Impacted Payers regarding written notice could provide useful examples for the level of specificity plans could use in denials. The Final Rule did not add a new regulatory definition for a "specific reason for denial," but CMS stated that for the purposes of the Final Rule, a "specific reason for denial" could include:

- Reference to the specific plan provisions on which the denial is based;
- Information about or the citation to formal coverage criteria;
- How documentation in the medical record did not support the plan of care for the therapy or service;
- A narrative explanation of why the request was denied;
- Why the plan deemed the service not to be necessary or that the claim history demonstrated that the patient had already received a similar service or item.

c. Starting in 2026, Payers Must Annually Publicly Report Certain Prior Authorization Metrics.

By March 31, 2026, Impacted Payers must annually report and post certain aggregated prior authorization metrics on their public websites, including the following:

- A list of all items and services that require prior authorization;
- The percentage of standard prior authorization requests that were (1) approved, (2) denied, and (3) approved after appeal;
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved;
- The percentage of expedited prior authorization requests that were (1) approved and (2) denied;
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations;
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan, or issuer, for expedited prior authorizations.

Impacted Payers must report data for each metric in aggregate for all items and services. MA organizations must report at the contract level, state Medicaid and CHIP FFS programs must report at the state level, Medicaid managed care plans and CHIP managed care entities must report at the plan level, and QHP issuers on the FFEs must report at the issuer level. CMS stated that public availability of this information would benefit patients in selecting plans and providers determining when and whether to contract with a payer.

In its comment letter, AAHKS asked CMS to require adoption of a standardized format for aggregated report data to ensure consistency of data and allow meaningful comparison between plans. Otherwise, providers and other stakeholders may face additional burdens in trying to access and analyze payer performance. CMS decline to impose such standardized format in the Final Rule, inviting plans instead to adopt standards used by the Medicare FFS program in reporting prior authorization metrics. CMS added that it may require standardized format in the future.

2. The Final Rule updates certain payer Application Programming Interface ("API") requirements to facilitate greater exchange of certain patient information between payers, patients, and providers.

a. In 2027, Impacted Payers must implement and maintain a Prior Authorization API to enable automation of certain processes for providers to facilitate the exchange of prior authorization requests and decisions from provider EHRs and practice management system.

In addition to being able to communicate whether the payer approves the prior authorization request, denies the request (with the specific reason), and requests more information, the Prior Authorization API must:

- Be populated with the payer's list of covered items and services (excluding drugs) that require prior authorization;
- Be able to identify all documentation required for approval of any items or services that require prior authorization;
- Support HIPAA-compliant prior authorization requests and responses.

In the Final Rule, CMS set forth additional operational and technical requirements for payers implementing the Prior Authorization API and provided additional details and considerations regarding technical specifications to enable information exchange between parties—including providers.

b. Beginning on January 1, 2027, Impacted Payers must make prior authorization information available through Patient Access API and must implement and maintain a Provider Access API to share certain patient data with the patient's in-network providers such as individual claims and encounter data and certain prior authorization information.

Notably, providers' information systems must meet certain technical specifications to use and exchange data through payers' Prior Authorization API, Patient Access API and Provider Access API.[5] CMS has suggested that forthcoming rulemaking to implement the No Surprises Act's good faith estimate requirement for covered patients may mandate providers' and facilities' adoption of API with certain standards and specifications to enable the exchange of information between providers and payers and between providers and facilities.

The good faith estimate of charges for care for covered patients will require all providers and facilities to provide detailed good faith estimates of scheduled services and all services reasonably expected to be furnished in conjunction with scheduled services by any provider or

[5] Request for Information; Advanced Explanation of Benefits and Good Faith Estimate for Covered Individuals, 87 Fed. Reg. 56905 (Sept. 16, 2022), https://www.federalregister.gov/documents/2022/09/16/2022-19798/request-for-information-advanced-explanation-of-benefits-and-good-faith-estimate-for-covered.

facility to patients covered by commercial coverage (such as individual, group, and employer plans). Timeframes for the good faith estimate includes a 1-day deadline to obtain information from co-providers and facilities and between 1 to 3 total days to prepare and transmit the good faith estimate to the patient's plan—depending on the length of time between scheduling and the date of service.

3. Other Updates from the Final Rule

CMS added a new "Electronic Prior Authorization," to the HIE objective for the MIPS Promoting Interoperability performance category and the Medicare Promoting Interoperability Program.

CMS previously solicited comments on the potential for gold-carding or prior authorization exemption programs. AAHKS responded that more wide-spread adoption of gold-carding programs would allow providers who have demonstrated compliance with plan requirements to be exempt from prior authorization and provide more streamlined medical necessity review processes. Nevertheless, CMS took no action in the Final Rule and gold-carding and stated that it will consider all comments on that topic for possible future rulemaking.

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