March 13, 2023

VIA E-MAIL FILING

Attention: CMS-0057-P
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: **Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard**

  The American Association of Hip and Knee Surgeons (AAHKS) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) Office on the proposed rule on "*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*" (the "Proposed Rule").[1]

  AAHKS is the foremost national specialty organization of more than 4,800 physicians with expertise in total joint arthroplasty (TJA) procedures. Our members account for the majority of Medicare total hip and total knee arthroplasty procedures each year. Many of our members conduct research in this area and are experts in using evidence based medicine to better define the risks and benefits of treatments for patients suffering from lower extremity joint conditions. In all of our comments, AAHKS is guided by its three principles:

- Payment reform is most effective when physician-led;
- The burden of excessive physician reporting on metrics detracts from care; and
- Patient access, especially for high-risk patients, and physician incentives must remain a focus.

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[1] 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, 87 Fed. Reg. 76238 (Dec. 13, 2022) [hereinafter, the "Proposed Rule"].

Our general comments are summarized as follows:

- AAHKS supports CMS' proposals to improve the prior authorization process
    - AAHKS supports CMS' proposed requirement for payers to adopt a Prior Authorization Requirements, Documentation, and Decision (PARDD) Application Programming Interface (API) to streamline and reduce critical burdens associated with the current prior authorization framework
    - AAHKS supports CMS' current proposal to require payers to include certain information with prior authorization denials as a first step to precede future CMS actions to ensure payers' prior authorization clinical criteria substantively rely on peer-reviewed, evidence-based guidelines reviewed by qualified experts and used by payer staff with adequate, appropriate, and specific qualifications to assess prior authorization requests
    - AAHKS supports CMS' establishment of specific prior authorization timeframes to reduce the unpredictable and lengthy amount of time AAHKS members and their patients often wait to receive payer decisions
    - AAHKS supports CMS' proposed requirement for payers to publicly report prior authorization metrics and encourages CMS to take steps to ensure payers use useful, efficient formats that promote transparency and impose no additional burdens on stakeholders seeking to evaluate such data
    - AAHKS supports gold-carding programs and encourages CMS to examine implementation of such systems at the state-level and by current Medicare Advantage (MA) plans
- While AAHKS supports CMS' continued efforts to reduce barriers and burdens associated with prior authorization, AAHKS encourages CMS to ensure the agency takes patient and provider impacts into account when considering imposing any future provider-side changes to advance interoperability

I.   Improving the Prior Authorization Process

Overall, AAHKS supports CMS' proposals to "improv[e] the prior authorization process." As discussed below, AAHKS believes the proposals—including the required adoption of PARDD API and changes that address timing, denials, and other administrative issues—directly and specifically address concerns previously identified by the Office of the National Coordinator ("ONC") and AAHKS members as critical barriers to care delivery under the current prior authorization framework. In its *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs* ("ONC HIT Strategy"), ONC cited key administrative burdens and challenges under the current prior authorization framework, which included (1) difficulty determining whether an item or service requires prior authorization; (2) difficulty determining payer-specific prior authorization requirements for items and services; (3) the inefficient use of provider and staff time to navigate communications channels such as fax, telephone, and various web portals; and (4) unpredictable and lengthy amounts of time to receive payer decisions.[2]
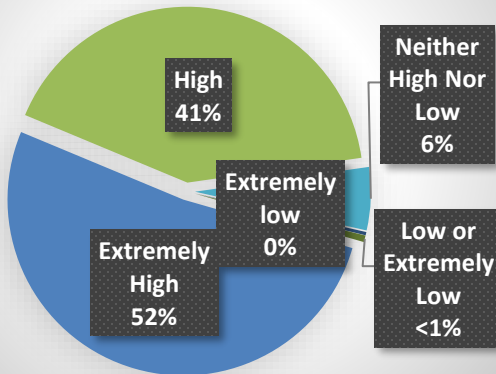
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[2] *See* ONC, Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria, 87 Fed. Reg. 3475 (Jan. 24, 2022); *see also* ONC, Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, (Feb. 2020'), https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf [hereinafter "ONC HIT Strategy"].

AAHKS members who have experienced the very administrative burdens cited by ONC remain encouraged by the value CMS has placed on data from provider organizations to better understand provider burdens under the current prior authorization framework. Consistent with the 2018 and 2020 American Medical Association (AMA) survey findings CMS referenced throughout the Proposed Rule, AAHKS members have faced high administrative burdens when attempting to comply with existing prior authorization requirements. When AAHKS conducted its own member survey in 2022 (the "2022 AAHKS Survey"), approximately 52% of respondents described burdens associated with the prior authorization as being "extremely high," while 42% of respondents described the burdens to be "high." *See* Figure 1. Further, approximately 70% of respondents reported employing full-time staff dedicated exclusively to prior authorization.

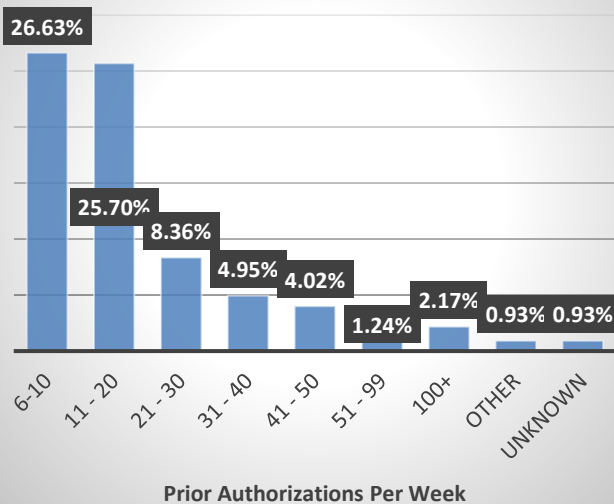## Figure 1. 2022 AAHKS Survey Results - Provider Burdens Associated with Prior Authorization

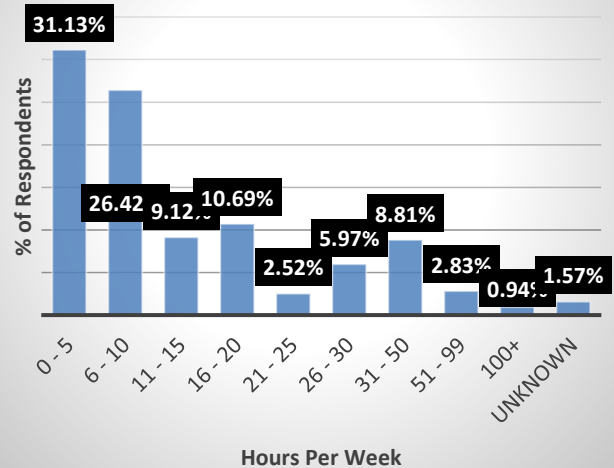**A. How would you describe the burden associated with prior authorizations in your practice?**

- High 41%
- Neither High Nor Low 6%
- Extremely low 0%
- Low or Extremely Low <1%
- Extremely High 52%

B. Do you have staff members in your practice who work exclusively on prior authorizations?

- No 27%
- Yes 70%
- Don't know 3%
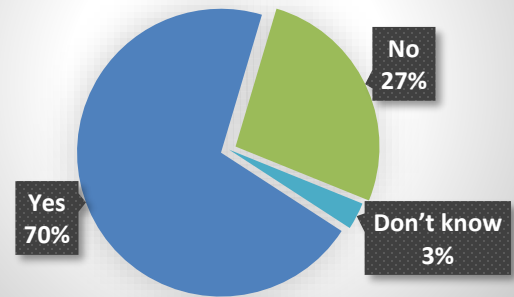
C. On average, how many prior authorizations do you or your staff complete each week for your patients?

Prior Authorizations Per Week	%
6-10	26.63%
11 - 20	25.70%
21 - 30	8.36%
31 - 40	4.95%
41 - 50	4.02%
51 - 99	1.24%
100+	2.17%
OTHER	0.93%
UNKNOWN	0.93%

D. On average, how many hours per week do you or your clinical staff spend completing prior authorizations for your patients?

Hours Per Week	% of Respondents
0 - 5	31.13%
6 - 10	26.42%
11 - 15	9.12%
16 - 20	10.69%
21 - 25	2.52%
26 - 30	5.97%
31 - 50	8.81%
51 - 99	2.83%
100+	0.94%
UNKNOWN	1.57%

AAHKS appreciates CMS' and HHS' continued efforts and engagement to advance strategies that will ultimately better enable providers to keep patients—rather than administrative work—at the center care delivery. AAHKS previously submitted comments to ONC's "Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria" (the "Letter to ONC") and the prior authorization and utilization management provisions of CMS' "2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" proposed rule (the "2024 MA Rule Comments"). In those letters, we expressed AAHKS' concerns with common plan prior authorization practices. As detailed further below, AAHKS supports CMS' proposals in the Proposed Rule, which address many specific challenges AAHKS members face and—depending on the requirement—apply widely to Medicare Advantage, State Medicaid and CHIP Agencies, Medicaid and CHIP Managed Care Plans, and Qualified Health Plans (QHPs) on the Federally-facilitated Exchanges (collectively, the "Impacted Payers").

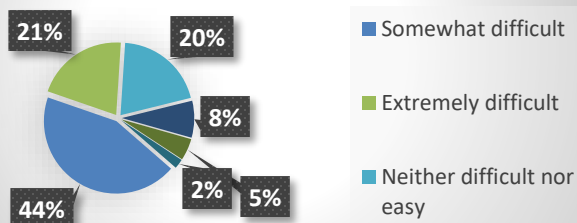### a. Prior Authorization Requirements, Documentation, and Decision API

CMS' Proposal: CMS proposes to require certain payers to implement and maintain a PARDD API to improve the prior authorization process between payers and providers, beginning January 1, 2026.

AAHKS supports CMS' proposal to require Impacted Payers' adoption of PARDD API. PARDD API would significantly improve the prior authorization process between payers and providers by enabling providers and their staff to (1) to automate certain tasks, including compiling data needed for prior authorization transactions; (2) query a particular payer's system to determine whether prior authorization may be required for certain items or services; and (3) identify documentation requirements. The API would also enable payers to provide the status of a prior authorization request.

AAHKS believes CMS' proposed changes directly address burdens associated with determining whether an item or service requires prior authorization and payer-specific prior authorization requirements as cited by ONC and experienced by AAHKS members. Approximately 65% of respondents in the 2022 AAHKS Survey reported determining whether certain treatments require prior authorization to be either "somewhat difficult" or "extremely difficult." *See* Figure 2(A). Survey results suggest such burdens have increasingly worsened as approximately 95% of AAHKS' respondents reported that the proportion of cases requiring prior authorization "increased significantly" or "increased somewhat" over the past 5 years. *See* Figure 2(B).

Figure 2: 2022 AAHKS Survey Results – Concerns with Payer Prior Authorization Standards

A. How difficult is it for you and/or your staff to determine whether a treatment (e.g. surgery) requires prior authorization?

- Somewhat difficult
- Extremely difficult
- Neither difficult nor easy

(21%, 20%, 8%, 2%, 5%, 44%)

B. Has the percent of your cases requiring prior authorizations changed over the last 5 years?

- Increased significantly
- Increased somewhat
- No change

(4%, 1%, 26%, 69%)
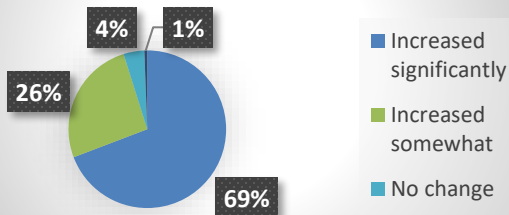
AAHKS believes that improved clarity regarding varying payers' respective prior authorization requirements can reduce the time spent by patients and providers navigating the process and provide providers and patients with a greater understanding of when prior authorization may be required ahead of time. Adoption of such changes may better enable providers and patients to plan, coordinate, and focus on the patient-provider relationship without the unexpected need for prior authorization interrupting providers' workflow and impeding patients' care.

b. Reason for Denial

CMS' Proposal: CMS proposes to require certain payers to use the PARDD API to compile necessary data for the transaction response to the provider in satisfaction of current Federal and state notice requirements as applicable to each type of Impacted Payer. Regardless of the method used to send the prior authorization decision, Impacted Payers would be required to include a specific reason for the denial. Information sent with denials must also include "whether an authorization request has been approved (and for how long), denied, with a reason for the denial, or request more information from the provider to support the prior authorization request."[3]

AAHKS strongly supports requiring Impacted Payers to provide a specific reason and the associated information with denied prior authorization decisions. Such changes will give providers and their staff greater insight into payers' denials. However, as CMS' proposal builds off existing federal and state requirements but does not require alteration of payers' existing substantive prior authorization clinical criteria requirements, AAHKS must view CMS' proposal regarding denials as one step in the right direction to improve prior authorization. AAHKS believes CMS' further adoption of additional requirements—as described below—remains critical to successful reform of prior authorization that prioritizes timely patient care unimpeded by administrative delays.

AAHKS strongly urges CMS to require Impacted Payers—including MA plans—to include the applicable coverage determination policy with each denial and to make public their coverage determination policies, including the evidence utilized to create such policies. AAHKS believes that requiring payers to include the applicable coverage determination policy with each denial would build off of the insight CMS' proposed changes seek to provide and would yield a substantially greater amount of useful information to ensure providers and their staff understand the reason for a prior authorization denial. Providing this information with each denial and/or making such information publicly available would better streamline the ability of providers and their staff to respond to and appeal prior authorization denials and to proactively work to avoid recurrent denials in the future.

AAHKS also encourages CMS to recommend Impacted Payers base substantive prior authorization criteria on peer-reviewed, evidence-based medicine and guidelines from national medical specialty societies reviewed by qualified experts. Improving substantive alignment of payer clinical criteria with peer-reviewed, evidence-based guidelines could reduce denials altogether—potentially decreasing delays associated with prior authorization denials and appeals and leaving more time for patients. Less than 1% of respondents to the 2022 AAHKS Survey stated health payers always base prior authorization criteria on evidence-based medicine and/or guidelines from national medical specialty societies, while a significant 46% of respondents stated payers rarely used such data in prior authorization criteria. Approximately 87% of 2022 AAHKS Survey respondents perceive prior authorization of having a "significant negative impact" or a "somewhat negative impact" on clinical outcomes. *See* Figure 3. AAHKS
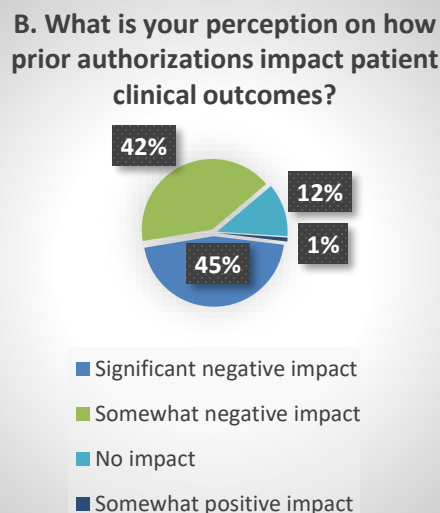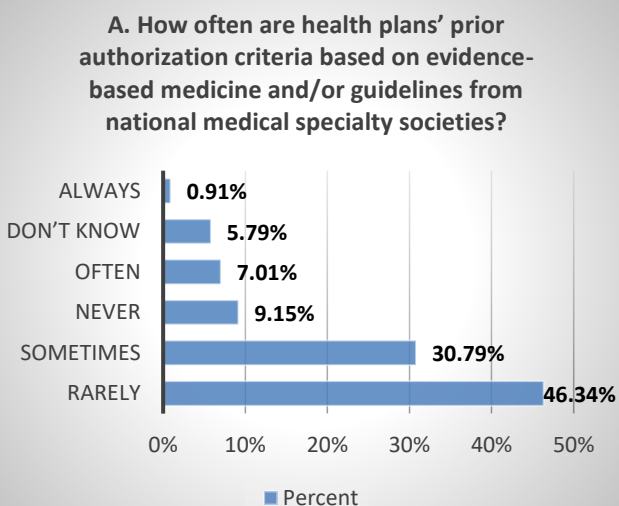
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[3] Proposed Rule at 76293.

believes the overall inconsistency and lack of transparency regarding the criteria and expertise upon which payers develop their prior authorization standards indicate a significant need to streamline prior authorization according to the best evidence-based practices. AAHKS also recommends that HHS ensure that the payer staff who review and make determinations in response to prior authorization requests have the adequate, appropriate, and specific qualifications required to be able to make such determinations using payers' evidenced-based clinical criteria.

AAHKS believes the accessibility and insight into applicable coverage determination policies and payers' substantive reliance on peer-reviewed, evidence-based medicine and guidelines to create such policies would enable stakeholders and patients to better understand and address payers' consideration of certain factors when denying claims—such as the site of service. For example, a forthcoming internal AAHKS research paper analyzing facility-specific issues found that 12% of inpatient prior authorization requests analyzed were approved for "outpatient-only" with little logic or reasoning provided with regard to the decision-making process. AAHKS fears that—in light of the removal of total knee arthroplasty and hip arthroplasty from the Medicare Inpatient Only list and recent trends toward outpatient surgery with few guidelines as to what is medically appropriate or safe—such occurrences could become more frequent. As such, AAHKS believes its recommendations for CMS to require payers' disclosure of certain information and reliance on evidence-based clinical criteria could provide stakeholders with the information needed to work towards ensuring prior authorization decisions always prioritize the interest of the patient while using the best, evidenced-based clinical practices.

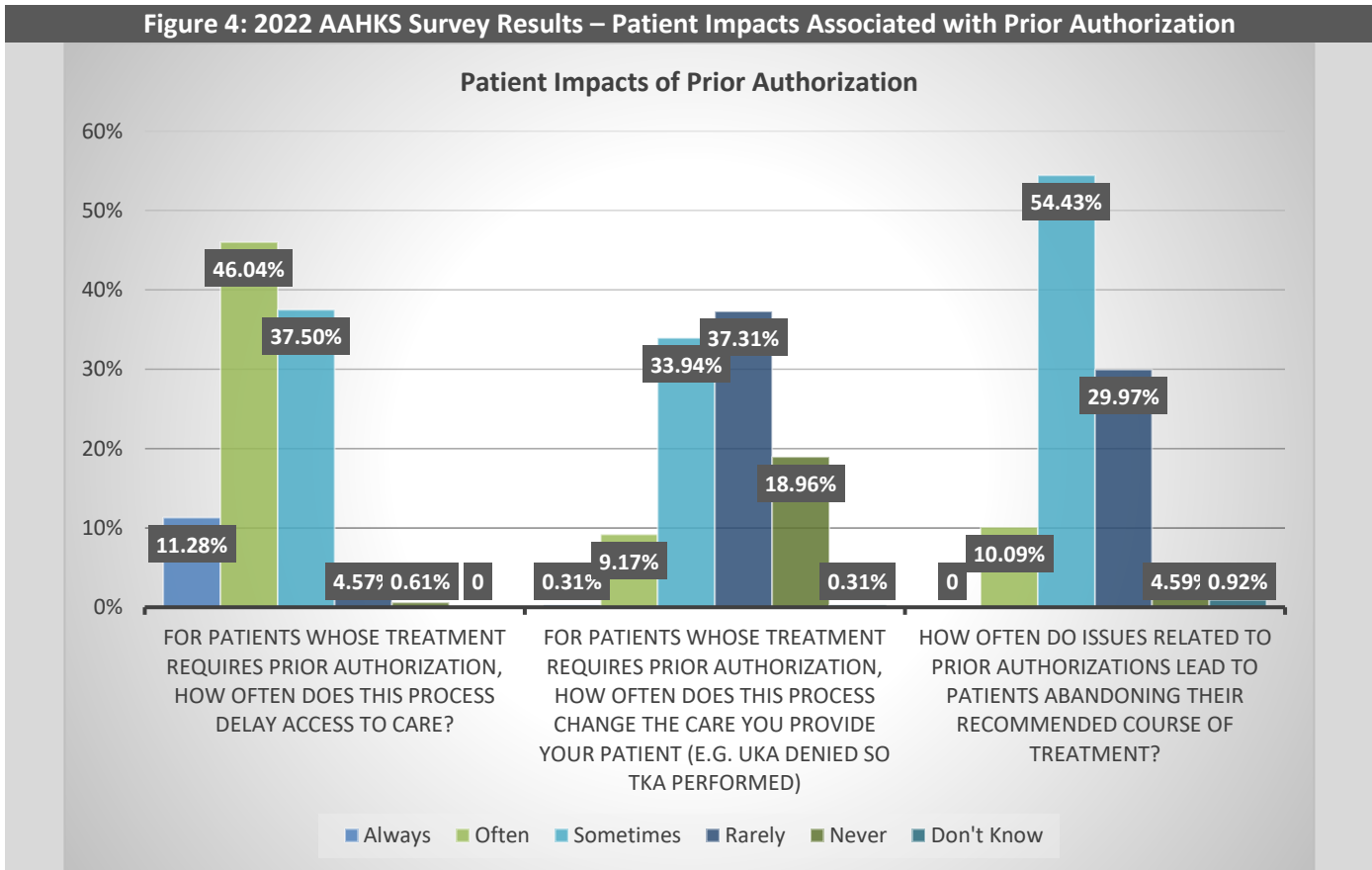| Figure 3: 2022 AAHKS Survey Results – Clinical Considerations |
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A. How often are health plans' prior authorization criteria based on evidence-based medicine and/or guidelines from national medical specialty societies?

Category	Percent
ALWAYS	0.91%
DON'T KNOW	5.79%
OFTEN	7.01%
NEVER	9.15%
SOMETIMES	30.79%
RARELY	46.34%

B. What is your perception on how prior authorizations impact patient clinical outcomes?

- Significant negative impact — 45%
- Somewhat negative impact — 42%
- No impact — 12%
- Somewhat positive impact — 1%

c. **Requirements for Timing of Notifications Related to Prior Authorization Decisions**

CMS' Proposal: CMS proposes to require Impacted Payers except QHPs to send prior authorization decisions within 72 hours for expedited requests and 7 calendar days for standard requests.

AAHKS supports CMS' proposed prior authorization notification requirements. CMS' proposal specifically addresses the unpredictable and lengthy amounts of time in which providers wait to receive payer decisions, as noted by ONC and experienced by AAHKS members. In AAHKS' Letter to ONC, AAHKS urged "HHS to impose timelines on payers to reduce delays to patient care that result from prior authorization requirements." Data from the 2022 AAHKS Survey highlights the uncertainty and delays AAHKS members and their patients experience under the current prior authorization framework. Approximately 57% of respondents to the 2022 AAHKS Survey indicated patients whose treatment requires prior authorization always or often experience delays in access to care. While 37% of respondents indicated prior authorization would rarely change the care the provider would provide to their patient, almost one-third answered "sometimes." Additionally concerning, 54% of respondents indicated issues related to prior authorizations sometimes leads to patients abandoning their recommended course of treatment. *See* Figure 4. Such delays or—in some case—abandonment of a recommended course of treatment, could ultimately jeopardize patients' health.

Figure 4: 2022 AAHKS Survey Results – Patient Impacts Associated with Prior Authorization

Patient Impacts of Prior Authorization

Legend: ■ Always ■ Often ■ Sometimes ■ Rarely ■ Never ■ Don't Know

FOR PATIENTS WHOSE TREATMENT REQUIRES PRIOR AUTHORIZATION, HOW OFTEN DOES THIS PROCESS DELAY ACCESS TO CARE?
- Always: 11.28%
- Often: 46.04%
- Sometimes: 37.50%
- Rarely: 4.57%
- Never: 0.61%
- Don't Know: 0

FOR PATIENTS WHOSE TREATMENT REQUIRES PRIOR AUTHORIZATION, HOW OFTEN DOES THIS PROCESS CHANGE THE CARE YOU PROVIDE YOUR PATIENT (E.G. UKA DENIED SO TKA PERFORMED)
- Always: 0.31%
- Often: 9.17%
- Sometimes: 33.94%
- Rarely: 37.31%
- Never: 18.96%
- Don't Know: 0.31%

HOW OFTEN DO ISSUES RELATED TO PRIOR AUTHORIZATIONS LEAD TO PATIENTS ABANDONING THEIR RECOMMENDED COURSE OF TREATMENT?
- Always: 0
- Often: 10.09%
- Sometimes: 54.43%
- Rarely: 29.97%
- Never: 4.59%
- Don't Know: 0.92%

d. **Public Reporting of Prior Authorization Metrics**

CMS' Proposal: CMS proposes to require payers to annually report certain aggregated metrics about prior authorization requests and a list of all items and services that require prior authorization on the payer's website or via a publicly accessible hyperlink starting on March 31, 2026.

AAHKS supports CMS' proposal to make such prior authorization reporting data available to the public. AAHKS agrees with CMS' view that availability of such data would be helpful for selecting payers and assessing payer trends. AAHKS also believes the data could help stakeholders and policymakers gain a better understanding of barriers in the prior authorization framework that may impede prompt patient care.

While AAHKS appreciates HHS' recommendation that payers consider "readability, and accessibility in preparing the data for viewing and comprehension,"[4] AAHKS encourages CMS to require adoption of a standardized format for aggregated data to ensure the lack of mandated consistency does not create a barrier or additional burdens for providers attempting to access and use the data. ONC noted in the ONC HIT Strategy that payers' and health IT developers' attempts to address prior authorization in an ad hoc manner resulted in a diversity of payer standards that reflected individual payer's technology considerations, lines of business, and customer-specific constraints.[5] AAHKS urges HHS to preemptively establish a level of conformity to avoid similar issues with future prior authorization data reports.

e. **"Gold-Carding" Programs for Prior Authorization**

CMS' Proposal: CMS seeks comments on ''gold-carding'' programs that relax or reduce a providers' prior authorization requirements if the provider has demonstrated a consistent pattern of compliance. Such programs relieve providers' requirements to submit prior authorization requests based on data indicating their adherence to submission requirements, appropriate utilization of items or services, or other evidence-driven criteria.

AAHKS strongly supports greater adoption of gold-carding programs, which AAHKS views as a promising tool that could ultimately alleviate significant burdens with respect to prior authorization on both the provider and plan side. 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 for providers. As such, AAHKS supports CMS' approach of encouraging payers to adopt gold-carding programs and encourages CMS to examine currently implemented models when assessing whether and how to incorporate a gold-carding measure as a factor in star quality ratings.

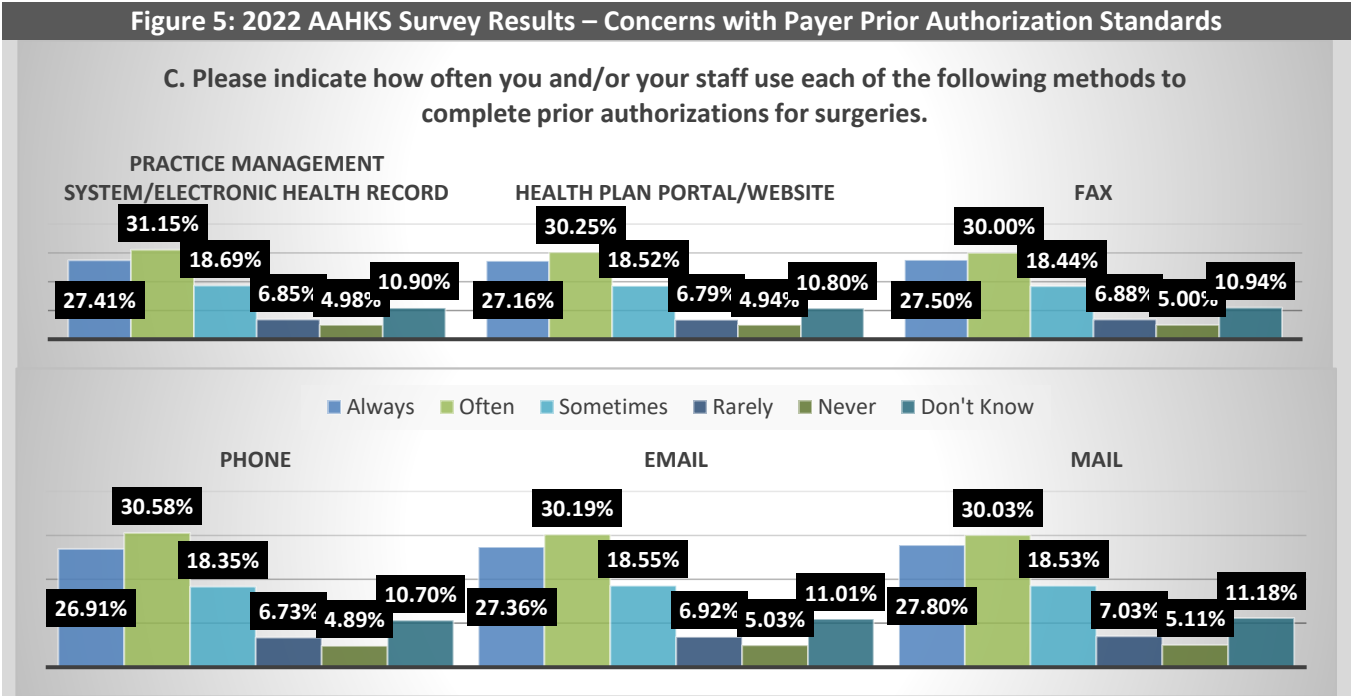---

[4] Proposed Rule at 76305.
[5] *See* ONC. Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs, (Feb. 2020'), https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf [hereinafter "ONC HIT Strategy"].

II. Patient Access API, Provider Access API, Payer to Payer Data Exchange, & Interoperability Standards

CMS' Proposal: CMS proposes to require impacted payers to implement and maintain a Fast Healthcare Interoperability Resources 1 (FHIR) API that satisfies specific technical standards to facilitate the exchange of certain data between payers, payers and providers, and payers and patients.

While AAHKS supports CMS' continued efforts to improve and streamline the communication pathways by advancing interoperability and requiring the Impacted Payers to adopt such standards, AAHKS encourages CMS, and HHS as a whole, to ensure the agency takes patient and provider impacts into account if the agency considers imposing provider-side changes to advance interoperability. As noted by HHS and other agencies in the request for information for the "Advanced Explanation of Benefits" issued in September 2022, "many providers and facilities exchange information with plans, issuers, and carriers using manual or paper-based technologies, such as portals, fax machines, or call centers… [u]p to 46 percent of prior authorization requests are still submitted by fax, and 60 percent require a telephone call during the prior authorization process."[6] While Figure 5 indicates the need for more standardized communication between payers and providers, it also highlights potential barriers to providers' similarly quick uptake of certain operability standards. For example, only approximately one-third of respondents to the 2022 AAHKS Survey stated they "always" use practice management systems/electronic health records (EHR(s)) or health payer portals/websites, which may indicate that a significant portion of providers may face issues transitioning to electronic prior authorization. In light of variation of providers' infrastructure, AAHKS urges that CMS consider anchoring future adoption of any provider-side standards on being patient-centered with regard to efficiency and simplicity.

Figure 5: 2022 AAHKS Survey Results – Concerns with Payer Prior Authorization Standards

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Additionally, AAHKS urges HHS to offer providers incentives and implement policies to ensure providers have adequate financial support if HHS imposes such provider-side requirements. Under the current framework of payers creating prior authorization standards and ONC creating corresponding certified EHR standards in response to payer covered standards, certified EHR developers pass costs on to providers who must purchase these systems. As AAHKS believes in keeping patients and the patient-provider relationship at the center of care, AAHKS urges HHS to create incentives and financial support to encourage and expedite putting any newly adopted functionalities into practice in the future.

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AAHKS appreciates your consideration of our comments. If you have any questions, you can reach Mike Zarski at mzarski@aahks.org or Joshua Kerr at jkerr@aahks.org.

Sincerely,

Bryan D. Springer, MD
President

Michael J. Zarski, JD
Executive Director