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AMERICAN ASSOCIATION OF
HIP AND KNEE SURGEONS

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May 29, 2024

VIA REGULATIONS.GOV FILING

Centers for Medicare & Medicaid Service
Department of Health and Human Services
Attention: CMS–4207–NC
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Medicare Program; Request for Information on Medicare Advantage Data

The American Association of Hip and Knee Surgeons ("AAHKS") appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services ("CMS") in response to CMS' Request for Information on Medicare Advantage Data (the "RFI")[1].

AAHKS is the foremost national specialty organization of more than 5,200 physicians with expertise in total joint arthroplasty (TJA) procedures. Many of our members conduct research in this area and are experts on the evidence-based medicine issues associated with the risks and benefits of treatments for patients suffering from lower extremity joint conditions. AAHKS is guided by four principles:

- Payment reform is most effective when physician-led;
- Reductions in physician reimbursement by public and private payers drives provider consolidation;
- 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.

AAHKS specifically writes to respond to the RFI's solicitation of comments regarding data related to prior authorization ("PA") in Medicare Advantage ("MA"). AAHKS appreciates CMS' efforts to seek and incorporate stakeholder feedback in future updates to the MA program as CMS continues to build off of the notable updates to PA in the *Advancing Interoperability and Improving Prior Authorization Processes* final rule (the "PA Final Rule")[2] finalized in January 2024 and CMS' *Contract Year 2024 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs* (the "MA Technical

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[1] Medicare Program; Request for Information on Medicare Advantage Data, 89 Fed. Reg. 5907 (Jan. 30, 2024), https://www.federalregister.gov/documents/2024/01/30/2024-01832/medicare-program-request-for-information-on-medicare-advantage-data.

[2] 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., (Feb. 8, 2024), https://www.federalregister.gov/public-inspection/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability (hereinafter, the "PA Final Rule).

Final Rule")[3] finalized in April 2023. AAHKS supports CMS' continuous efforts to make improvements to PA in the MA program and CMS' rulemaking has addressed many of the issues AAHKS members identified in a 2022 survey of our membership regarding PA practices. However, AAHKS believes additional changes related to the type of data reported by MA organizations and the manner in which MA organizations report such data could further advance the policy goals CMS highlighted in its recent rulemaking, promote transparency and accountability in the MA program, and help ensure that future updates to PA in the MA program better enable providers to keep patients—rather than administrative work—at the center care delivery.

AAHKS urges CMS to adopt the following policies summarized below to ensure future PA rulemaking continues to center the provider-patient relationship in the MA program:

- Require MA organizations to report more granular plan-level data on PA determinations and MA plans' PA determination process, including (a) reporting at the plan-level rather than the contract-level and (b) reporting additional item and service-specific data.
- Require MA organizations to report additional data related to MA plans' PA decision-making processes, including (a) data related to how MA organizations provide a "specific reason for denial" when denying a prior authorization request; (b) data related to the coverage criteria updates imposed by the MA Technical Final Rule; (c) data related to PA determinations involving site of service changes; and (d) data related to the qualifications of plans' staff that review and make prior authorization determinations and MA organizations' use of third parties to interpret and make PA determinations.
- Facilitate use of PA data by (a) standardizing reporting across MA organizations through regulations, guidance, and/or implementation guides; (b) posting reported PA data to CMS' website; and (c) requiring MA organizations to make coverage determination policies publicly available on their websites.

Below, AAHKS further details its policy recommendations:

1. **AAHKS urges CMS to require MA organizations to report more granular plan-level data on PA determinations and MA plans' PA determination processes.**

AAHKS urges CMS to build on the reporting requirements imposed by the PA Final Rule to ensure the availability of more granular data that can be compared at the plan-level. While the PA Final Rule requires MA organizations to annually report and post certain prior authorization metrics in aggregate for all items and services at the contract level on their website by March 31, 2026,[4] AAHKS believes more granular reporting of certain PA data can facilitate more efficient use by stakeholders to understand and analyze PA determination trends and MA plans' practices with regard to PA determination processes and considerations as updated by the MA Technical Final Rule.

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[3] 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 (hereinafter, the "MA Technical Final Rule).

[4] PA Final Rule at 8764.

a. AAHKS urges CMS to require MA organizations to report at the plan-level rather than the contract-level.

AAHKS urges CMS to require plan-level reporting of PA data reporting in the MA program. CMS stated in the PA Final Rule its expectation that providers would "use the prior authorization metrics to evaluate managed care plans and make decisions on whether to join or remain part of a plan's network."[5] However, unlike Medicaid managed care or CHIP managed care entities which will report at plan-level, CMS did not require plan-level reporting of PA data for the MA program. Rather, CMS required data reporting to be conducted at the contract-level. While AAHKS understands that contract-level reporting would be consistent with other reporting requirements to which MA organizations are already subject, AAHKS believes that a lack of plan-level data would inhibit providers' ability to use PA metrics in a meaningful way to compare across MA plans—and, much less, to make decisions on whether to participate in an MA plans' network as CMS intended.

CMS acknowledged the benefit of plan-level data in the PA Final Rule, stating that it "agree[d] that requiring Medicaid managed care plans and CHIP managed care entities to report at the plan level [would] allow beneficiaries and states to compare plans within the state."[6] Consistent with CMS' intentions underlying the data reporting requirements, AAHKS believes plan-level PA data reporting would better enable all stakeholders of the MA program, including providers and patients, to more meaningfully use the PA data by allowing direct comparison of metrics across plans.

b. AAHKS urges CMS to require MA organizations to report more granular item and service-specific data.

AAHKS urges CMS to require that MA organizations report more granular data. While AAHKS agrees aggregated data may inform stakeholders of some of the PA trends and practices of MA organizations, AAHKS believes the availability of more granular data will enable stakeholders to use the PA data to understand particular PA implications for certain items and services, particular settings, and when MA plans use certain clinical decision criteria. As such, AAHKS urges CMS to require MA organizations also report the following data fields:

- Item and service-specific average PA response times for both expedited and standard PA requests
- Item and service-specific rates of PA approvals, denials, and post-appeal approvals
- Item and service-specific information regarding site of care and whether the service is inpatient or outpatient
- Item and service-specific approval, denial, and post-appeal approval rates when "fully-established" coverage criteria applies (for example, denial rates of LCD #L36039, total joint arthroplasty)
- Item and service-specific approval, denial, and post-appeal approval rates when internal coverage criteria is used
- A list of the 100 most and least commonly denied items and services

Further, AAHKS believes that reporting of more granular data will enable CMS and stakeholders to better understand trends that support future adoption of PA policies. AAHKS agrees with other commenters referenced by CMS in the PA Final Rule that stated "that service-specific reporting will aid in

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[5] *Id.* at 8892.
[6] *Id.* at 8889.

identifying services for which there is a high rate of approval and for which prior authorization requirements may no longer be necessary, or for identifying critical services or items being routinely denied."[7] Specifically, AAHKS believes that more granular PA reporting will better enable identification of when policies such as "gold-carding" should be more widely adopted.

AAHKS strongly supports the use of "gold-carding" policies within the MA program to eliminate the PA process when providers have a high success rate (> 90 %) navigating PA. As AAHKS conveyed in its comments during rulemaking for the MA Technical Final Rule and the PA Final Rule when CMS specifically sought feedback on "gold-carding" policies, AAHKS views "gold-carding" 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. AAHKS encourages CMS to continue exploring its expansion of gold-carding within the MA program, because—as CMS noted in its proposed version of the PA Final Rule—"the use of gold-carding and similar prior authorization reduction programs could help alleviate provider burden" and through adoption of gold-carding approaches, "payers could join CMS in helping to build an infrastructure that would allow clinicians to deliver care in a timely and value-based manner."[8]

2. **AAHKS urges CMS to require MA organizations to report additional data related to MA plans' PA decision-making processes.**

AAHKS urges CMS to require MA organizations to report additional data regarding the "specific reason for denial" MA organizations provide in PA denials to ensure that providers can adequately respond to denials, understand MA organizations' PA coverage criteria, and reduce future issues with PA—particularly given the significant changes the MA Technical Rule made with regard to MA organizations' clinical criteria and PA decision-making.

a. *AAHKS urges CMS to require MA organizations to report additional data addressing denials in the PA process, including data related to how MA organizations provide a "specific reason for denial" when denying a prior authorization request.*

AAHKS urges CMS to require MA organizations to report additional data regarding the "specific reason for denial" MA organizations provide in PA denials. The PA Final Rule requires MA organizations to provide a specific reason for denied PA denials starting in 2026. While CMS stated that the denial would have to 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, CMS did not establish a regulatory definition for a "specific reason for denial."[9]

Instead, CMS provided guidance regarding what a "specific reason for denial" *could* include as used in the PA Final Rule. As such, AAHKS believes that CMS should require MA organizations to report item and service-specific data conveying (a) the frequency at which an MA organization includes or relies

[7] *Id.* at 8893.
[8] 87 Fed. Reg. 76238, 76307 (Dec. 13, 2022).
[9] PA Final Rule at 8872.

on one or a combination of the potential "specific reason[s] for denial" CMS provided in its guidance in the preamble to the PA Final Rule[10] and (b) the associated denial rates:

- 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

Additionally, AAHKS would strongly support CMS codifying that the "specific reason for denial" for MA organizations reflects the updates the MA Technical Final Rule made with respect to MA organizations' PA determinations. While AAHKS believes this additional data described above regarding MA organizations' "specific reason for denial" would provide CMS and stakeholders insight into MA organizations' PA practices, AAHKS urges CMS to update MA regulations to make clear the information plans should include in denials in light of both the PA Final Rule and the MA Technical Final Rule. Prior to the two rules, MA regulations already required MA plans to "provide [a] specific rationale for [a prior authorization] decision and include State or Federal law and/or Evidence of Coverage provisions to support [the] decision."[11] However, CMS did not propose a change to existing requirements related to denial notices" in the MA Technical Final Rule.

AAHKS agrees with CMS's statement in the MA Technical Final Rule that "[c]ommunicating all necessary information needed for the enrollee or provider to effectively appeal the decision, including the evidence used to support the internal coverage policy when applicable, is one of the purposes of the denial notice."[12] Further, failing to codify the material changes to the PA process imposed by the MA Technical Final Rule undermines the rule itself and may lead to disjointed and ineffective implementation that could leave providers with the same insufficient level of information in denials as before CMS finalized its rules. As such, AAHKS believes that CMS should formally codify such changes to the MA PA denial notice requirements to ensure that the "specific reason for denial" includes the following —among other factors in the MA Technical Final Rule:

- **Medical Necessity Determinations**: The coverage and benefit criteria; whether the provision of items or services was reasonable and necessary; factors the MA plan considered regarding the enrollee's medical history, physician recommendations, and clinical notes; information regarding review by a physician or other appropriate health care professional with expertise in the field of medicine or health care appropriate for the service at issue; and information regarding the involvement of the organization's medical director, if applicable.
- **Items And Services With Fully-Established Coverage Criteria**: The national coverage determination(s), local coverage determination(s), and/or other applicable coverage criteria in Medicare statutes and regulations used in the determination
- **Items And Services Subject to Internal Coverage Criteria:** The internal coverage criteria and evidence used to support the internal coverage policy, when applicable

[10] *Id.*
[11] CMS, Integrated Denial Notice Form (Mar. 3, 2023).
[12] MA Technical Final Rule at 22191.

b. <u>AAHKS urges CMS to require MA organizations to report additional data related to the coverage criteria updates imposed by the MA Technical Final Rule.</u>

AAHKS urges CMS to require reporting data relating to the coverage criteria updates imposed by the MA Technical Final Rule. AAHKS appreciated the updates in the MA Technical Final Rule that provided clarity with regard to the overlap between Traditional Medicare coverage policies and also established more rigorous requirements for MA plans' internal coverage policies. AAHKS believes that in order for CMS and stakeholders to understand the impacts of such changes and to identify potential issues with MA plans' internal coverage criteria, CMS should require that MA organizations to report certain relevant data as part of the PA reporting requirements imposed by the PA Final Rule. Specifically, AAHKS urges CMS to require MA organizations also report the following data fields:

- Item and service-specific approval, denial, and post-appeal approval rates when "fully-established" coverage criteria applies (for example, denial rates of LCD #L36039, total joint arthroplasty)
- Item and service-specific approval, denial, and post-appeal approval rates when MA plans use internal coverage criteria

c. <u>AAHKS urges CMS to require MA organizations to report additional data related PA determinations involving site of service changes</u>.

AAHKS urges CMS to require MA organizations to provide additional data regarding PA determinations involving a site of service change. Although the MA Technical Final Rule addressed some of AAHKS' site of service concerns, AAHKS seeks additional clarity on MA plans' practices of reimbursing a claim on an outpatient basis when a physician has ordered an inpatient procedure. As such, AAHKS specifically urges CMS to require MA organizations to report the following as part of its reporting requirements under the PA Final Rule:

- The rate at which MA plans decide to only reimburse a procedure on an outpatient basis when a physician has ordered an inpatient procedure
- Items and services with the highest frequency of site of service changes during PA

d. <u>AAHKS urges CMS to require MA organizations to report additional data related to the qualifications of plans' staff that review and make prior authorization determinations and to MA organizations' use of third parties to interpret and make PA determinations.</u>

AAHKS urges CMS to require MA organizations to report data related to the qualifications of MA plans' staff reviewing PA determinations and the use of third-party reviewers. The MA Technical Final Rule specified that "a denial based on a medical necessity determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the service at issue."[13] While CMS did not "require plans to provide documentation of the physician reviewer's compliance with qualification standards with each denial notice" in the MA Technical Final Rule as suggested by a commenter, AAHKS believes that additional information regarding the providers or professionals reviewing MA plans' PA requests will better inform future rulemaking as CMS continues to refine the PA clinical criteria requirements.

[13] *Id.* at 22195.

Similarly, to ensure reviewers have the adequate, appropriate, and specific qualifications required to be able to make PA determinations in alignment with the requesting provider, AAHKS also urges CMS to require plans to report data regarding use of third-party reviewers, as CMS may later seek to obtain more data regarding third party reviewers. As such, AAHKS believes CMS should require MA organizations to report the following as part of its reporting requirements under the PA Final Rule:

- Licensure-types of reviewers, organized by the licensure type of requesting providers
- Data relating to reviewers' formal medical training in the subject matter under review
- Data relating to the use of third parties, including the rates of use; denial, approval, and post-approval rates for PA determinations made by third parties; and the top items and services for which the MA plan uses third party reviewers

3. **AAHKS urges CMS to facilitate use of the PA data by a) standardizing reporting across MA organizations through regulations, guidance, and/or implementation guides; (b) by posting reported PA data to CMS' website; and (c) requiring MA organizations to make coverage determination policies publicly available on their website.**

    a. *AAHKS urges CMS to facilitate use of PA data by standardizing reporting across MA organizations through regulations, guidance, and/or implementation guides.*

AAHKS urges CMS to establish standardized reporting requirements to ensure patients' and providers' ability to access and use the reported PA aggregated metrics in a meaningful way. When finalizing the requirement for MA organizations to annually report and post certain aggregated prior authorization metrics on their public websites in the PA Final Rule, CMS did not provide guidance with respect to how MA organizations report and post the data. Instead, CMS "invite[d] payers to reference the presentation of the [Medicare FFS program's publicly prior authorization metrics] as they develop their public reporting strategy."[14] To ensure that the lack of mandated consistency does not create a barrier or additional burdens for providers attempting to access and use the data, AAHKS recommends that CMS issue regulations, guidance, and/or implementation guides that:

- Establish report formatting
- Specify consistent calculation of the metrics
- Ensures prominent placement of the data on payers' websites
- Indicates the cadence at which payers must refresh the publicly-reported data
- Establishes the method through which data is available (such as downloadable through Excel)

AAHKS believes that the lack of standardized reporting requirements may impede CMS' efforts to promote transparency through public reporting of aggregated metrics. In the PA Final Rule, CMS cited public reporting as "one of the most universal, effective means to demonstrate improvement or change" that "has value because it can provide a benchmark for patients or providers to understand, at a high level, the volume of services a payer approves or denies, the types of services it authorizes, or changes in those decisions over time."[15] Further, CMS stated its expectation that providers would "use the prior

[14] PA Final Rule at 8892.

[15] *Id.*

authorization metrics to evaluate managed care plans and make decisions on whether to join or remain part of a plan's network."[16]

Like other stakeholders cited by CMS in the PA Final Rule, AAHKS believes that the lack of standardized reporting requirements could "lead to a wide variation across impacted payers" and might impede providers' ability to actually use the data in a meaningful way. As noted by the Office of National Coordinator the Office of the National Coordinator ("ONC") in their *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*, payers' and health IT developers' attempts to address prior authorization in an ad hoc manner resulted in inconsistent payer standards that reflected individual payer's technology considerations, lines of business, and customer-specific constraints.[17] AAHKS urges CMS to preemptively establish a level of conformity to avoid similar issues with future prior authorization data reports, as it has across other transparency regulatory frameworks.

b. *AAHKS urges CMS to facilitate use of the reported PA data by posting reports to CMS' website.*

AAHKS urges CMS to ensure patients' and providers' ability to meaningfully access and use aggregated reported data by requiring MA organizations' reports to be posted to CMS' website and to be included in comparative data public reports. While the PA Final Rule requires MA organizations to annually report and post certain prior authorization metrics in aggregate for all items and services at the contract level on their website, CMS did not specify where or how the data must be posted, stating that CMS "anticipate[s] payers will identify the most appropriate locations on their website for the information to be public."[18] CMS also stated that it did not require payers to submit reports to a central website for publication based on CMS' belief that "patients likely would view their health plan and payer as the resource for information about their plan,"[19] but still urged "state Medicaid agencies to include the data on their websites […] to improve the value of information available to their patients."[20]

AAHKS believes that requiring patients and providers to access each MA organization's data on their website makes stakeholder use of the data burdensome and impedes effective and comparative use of the data—particularly in light of the lack of standardized reporting requirements. As such, AAHKS urges CMS to require MA organizations to submit data to a central website to reduce the burden for providers and payers seeking to use the aggregated data and to enable easy retrieval of data by physicians and patients.

c. *AAHKS urges CMS to facilitate use of PA data by requiring MA plans to make coverage determination policies publicly available on MA organization websites.*

AAHKS specifically urges CMS to require MA plans to make internal coverage criteria publicly available and accessible on their plan website, or–at a minimum–to require MA plans to include a notification on the MA plan website that such coverage determination policies are available upon request.

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[16] *Id.*

[17] 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"].

[18] PA Final Rule at 8892.

[19] *Id.* at 8893.

[20] *Id.*

While the MA Technical Final Rule made significant improvements in clarifying and streamlining MA plans' creation and use of internal coverage criteria by requiring MA plans make internal coverage criteria "publicly accessible," AAHKS believes CMS may have impeded optimized implementation of its policy updates by deciding not to specify how MA plans make internal coverage criteria "publicly accessible."[21]

Although CMS noted that commenters requested CMS to "provide guidance on how this information should be shared publicly [as] some resources may be behind a paywall," or require MA plans to post the "information in a visible location on their websites," CMS stated in the MA Technical Final Rule that "[i]n an effort to provide plans with flexibility, [CMS] decline[d] to require specific mechanisms for how the information is made publicly available" and recommended "MA plans refer to the coverage criteria and summary of evidence presented by MACs as a guide and best practice for how to present this information publicly."[22]

AAHKS believes that without accessibility to MA organizations' internal coverage criteria, providers may still face the same administrative burdens with regard to MA plans' use of internal coverage criteria that predated the MA Technical Final Rule—particularly if such policies are behind paywalls or not otherwise available on an MA plan's website.

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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,

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President

Michael J. Zarski, JD
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cc: Meena Seshamani, MD, PhD, Director, Center for Medicare
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[21] MA Technical Final Rule at 22198.
[22] *Id.*