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May 29, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4207–NC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Request for Information on Medicare Advantage Data [CMS–4207–NC]

Dear Administrator Brooks-LaSure:

The Large Urology Group Practice Association (LUGPA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) Request for Information on Medicare Advantage Data ("RFI"),[1] which follows CMS's 2022 General Medicare Advantage (MA) RFI.[2]

As of 2024, CMS estimates that 50% of all Medicare beneficiaries are currently enrolled in MA plans.[3] LUGPA represents 150 urology group practices in the United States, with more than 2,100 physicians who, collectively, provide approximately 35% of the nation's Medicare urology services. Furthermore, LUGPA's members provide most of the GU care delivered in the independent physician office setting. Given this, we appreciate CMS's ongoing efforts to improve MA data capabilities by requiring MA organizations to improve prior authorization processes.

In comments submitted for CMS's 2022 Interoperability and Prior Authorization Proposed Rule,[4] LUGPA expressed support for CMS's stated goal of streamlining the prior authorization process to reduce provider burden and allow providers to better focus on administering patient care. LUGPA was pleased that CMS in the 2024 Interoperability and Prior Authorization Final Rule finalized requirements for impacted payers, including MA plans,[5] to implement the Prior Authorization Requirements, Documentation, and Decision (PARDD) API and provide specific reasons for prior authorization denials.[6]

[1] Medicare Program; Request for Information on Medicare Advantage Data, 89 Fed. Reg. 5907 (Jan. 30, 2024).

[2] 2022 General Medicare Advantage RFI, 87 Fed. Reg. 46918 (Aug. 31, 2022).

[3] CMS, *Medicare Advantage and Medicare Prescription Drug Programs to Remain Stable in 2024* (Sep. 26, 2023), available at: https://www.cms.gov/newsroom/press-releases/medicare-advantage-and-medicare-prescription-drug-programs-remain-stable-2024.

[4] Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule ("2022 Proposed Rule"), 87 Fed. Reg. 76238 (Dec. 13, 2022).

[5] Defined as Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs).

[6] Advancing Interoperability and Improving Prior Authorization Processes Final Rule ("2024 Final Rule"), 89 Fed. Reg. 8758 (Feb. 8, 2024).

In this RFI, CMS is seeking comments on various aspects of data related to the MA program, including data-related recommendations pertaining to beneficiary access to care, as well as prior authorization and utilization management. LUGPA strongly encourages CMS to adopt policies to further increase transparency and streamline prior authorization processes for providers to submit prior authorization requests and ensure that MA enrollees do not experience unnecessary delays in care. Specifically, LUGPA respectfully requests that CMS prioritize enforcement of its finalized policies for requiring MA plans to issue prior authorization determinations within a set timeframe and to provide a clear rationale for any prior authorization denials. Additionally, LUGPA asks that CMS take steps to limit unnecessary and excessively burdensome prior authorization documentation and process requirements and to establish standards for payer representatives who review prior authorization requests and issue determinations. Further, LUGPA respectfully requests that CMS prioritize data collection related to prior authorization requests to MA plans for specialty care.

I. Background on LUGPA

LUGPA was formed in 2008 as a way to facilitate communication between independent urology-focused (GU) groups of ten or more providers. This served the complementary priorities of: (1) the promotion of clinical and operational benchmarking to guide best practices; (2) the establishment and promulgation of quality guidelines; and (3) the utilization of resources for advocacy and communication in the legislative and regulatory arena. LUGPA was thereby able to ensure that its providers had an opportunity to advocate on behalf of their patients and their specialty at a national level.

Since that time, LUGPA has expanded its mission to incorporate any non-hospital-based group practice who shares the foundational principles of commitment to providing integrated and comprehensive GU services to those impacted by genitourinary diseases and conditions. LUGPA has gained membership steadily; it currently includes over 150 urology group practices in the United States, representing more than 2,100 physicians who, collectively, provide approximately 35% of the nation's Medicare urology services.[7] Furthermore, LUGPA's members provide most of the GU care delivered in the independent physician office setting.

As healthcare reform efforts in the US have evolved to redirect focus toward the development and promotion of outcome-driven, "best-practice" patient care, delivered in the most cost-effective setting, LUGPA practices have consistently been leaders in innovative and adaptive care models. Expanding both the range of procedures and the integration of care that can be safely and effectively provided in the independent physician setting has resulted in improved access while demonstrating concomitant reduction in the cost of care delivery, as well as improved outcomes.

In addition, LUGPA practices have been at the forefront of adopting team-based healthcare, with broad incorporation of other physician specialists and a variety of advanced practice providers, maximizing both convenience and accessibility to expert treatment for the full spectrum of GU conditions. LUGPA practices have embraced value-based care models, and the organization was among the first to create a physician-focused payment model. As such, LUGPA has continued to be a leader in the development of high-quality, cost-effective alternatives for care delivery as a

[7] CMS. Utilization numbers based on cross-referencing LUGPA membership data with 2020 Medicare Physician & Other Practitioners Public Use Files. Accessed at: https://data.cms.gov/provider-summary-by-type-of-service/medicarephysician- other-practitioners, September 1, 2020.

counterbalance to the cost increases associated with the trend towards consolidation of health care services.

II. CMS Should Prioritize Data Collection on Specialty Health Services to Support Efforts to Further Increase Transparency and Streamline Processes for Prior Authorization Requests

Utilization management techniques, such as prior authorization, can be disproportionately applied to patients in MA plans and overly burdensome on providers. In 2021, over 35 million prior authorization requests were sent to MA plans, and 2 million were denied.[8] Of these denials, approximately 212,000 were appealed, the majority of which (over 173,000, or 82%) resulted in the denial being partially or fully overturned.[9] According to a recent report from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), MA organizations have delayed or denied prior authorization requests for medical services that were within Medicare coverage rules. Indeed, the HHS-OIG report explains how such denials "may prevent or delay beneficiaries from receiving medically necessary care and can burden providers," and that "avoidable delays and extra steps create friction in the program and may create an administrative burden" for providers and beneficiaries.[10]

In the 2024 Final Rule, CMS finalized several policies to improve transparency and streamline prior authorization processes, which can mitigate such delays and ease provider burdens. Specifically, CMS finalized requirements for MA plans to "provide a specific reason to the provider when denying a [request for] prior authorization."[11] Starting in 2026, most impacted payers, including MA plans, must notify patients and providers of prior authorization determinations with 72 hours for expedited requests and seven calendar days for standard requests (unless state laws impose shorter timeframes), pursuant to the 2024 Final Rule.[12] CMS in the 2024 Final Rule additionally reaffirms existing requirements, under 42 CFR § 422.566, that a "physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services being requested, including knowledge of Medicare coverage criteria" review prior authorization denials based on medical necessity before the MA plan issues the denials.[13]

LUGPA thanks CMS for finalizing processes to improve prior authorization requests and reaffirming existing obligations for MA plans, and we respectfully request that CMS prioritize enforcement of these requirements for issuing a prior authorization determination within a set timeframe and for providing a clear rationale for any prior authorization denial.

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[8] Jeannie Fuglesten Biniek and Nolan Sroczynski, *Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021*, KFF (Feb. 2, 2023), available at: https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/.

[9] *Id.*

[10] HHS-OIG, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care* (Apr. 2022), available at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[11] 2024 Final Rule at 8873 (Feb. 8, 2024).

[12] *Id.* at 8878.

[13] 42 CFR § 422.566(d); *see also* 2024 Final Rule at 8872 (Feb. 8, 2024).

The burdensome processes for prior authorization requests—and subsequent appeals processes—lead to delays in care, but the high overall rate of prior authorization approvals (and associated denial overturns) for MA plans suggests that MA plans are employing prior authorization as a stalling tactic at best, and as denial mechanism at worst, particularly for enrollees and providers that lack the resources to surmount the hurdles placed by MA plans. Therefore, LUGPA respectfully recommends that CMS consider limiting prior authorization requirements to certain experimental or exceptional circumstances. Such limitations would establish necessary guardrails around use in MA populations, which could thereby prevent any unnecessary delays in care. For patients who require specialty health services, removing such delays is especially critical.

In response to this RFI, we recommend that CMS prioritize continued data collection on prior authorization denials in MA, in particular for specialty health services, such as GU services. We further recommend that CMS prioritize collecting data on MA plan requests for additional documentation to support medical necessity determinations, denials based on medical necessity and subsequent appeals, and how many of those medical cases already had sufficient evidence to establish medical necessity, compared to patients requesting the same services under Traditional (fee-for-service, or "FFS") Medicare, with a focus on specialty health services.

III. CMS Should Further Limit Excessively Burdensome Prior Authorization Documentation and Appeals Requirements and Establish Standards for Subject-Matter Expertise

In response to the 2022 Proposed Rule, LUGPA expressed support for CMS's proposal to require impacted payers use a PARDD API, and we requested that CMS take additional steps to limit impacted payers from imposing unnecessary and excessively burdensome prior authorization documentation and process requirements. We appreciate CMS finalizing the requirement for using the PARDD API in the 2024 Final Rule, as this is indeed a necessary step toward streamlining the prior authorization process. However, the PARDD API does not address the fact that some payers implement and impose burdensome and unnecessary documentation, clinical criteria, and other requirements for prior authorization; these requirements often lead to unnecessary delays and improper denials of reasonable and necessary care.

Indeed, HHS-OIG found that some MA plans have denied prior authorization requests for services that would have been approved for FFS beneficiaries; this can occur when MA organizations make determinations using clinical criteria not contained in Medicare coverage rules.[14] Further, HHS-OIG found that some MA organizations requested additional, unnecessary documentation before making a decision, then denied prior authorization requests for lack of such documentation; however, HHS-OIG physicians determined there was sufficient clinical evidence in case files to establish medical necessity.[15]

In addition to the burdensome request process, the appeals process is onerous; it is more difficult for specialty physicians appeal prior authorization denials, as the payer representative is virtually

[14] HHS-OIG, *Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care* (Apr. 2022), available at: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

[15] *Id.* at 11.

never a subject-matter expert, nor a physician. As a result, specialists are forced to spend considerable time explaining current best practices to individuals who are unable to evaluate the information as it relates to the requested clinical activity or service. LUGPA therefore respectfully requests that CMS require MA plans to substantively govern their prior authorization policies, including establishing standards to ensure that payer representatives reviewing prior authorization requests for specialty care have the appropriate subject-matter expertise to evaluate the documentation and issue determinations.

In response to this RFI, we encourage CMS to ensure that it is collecting and reporting to the public information on MA plan requirements for prior authorization. In addition to our above recommendations, we further recommend that CMS collect data on additional prior authorization processes established by MA plans, such as the type of additional documentation requested, and the clinical background and training of the individuals authorized to review the documentation and issue denials or approvals.

IV. CMS Should Collect Data Related to Challenges for Patients Who Develop Chronic Conditions While Enrolled in Medicare Advantage Plans

As noted above, in 2023, an estimated half of all Medicare beneficiaries enrolled in MA plans, and by 2025, MA plans are anticipated to account for more than half of all Medicare beneficiaries.[16] However, MA plans generally require prior authorization for certain health services or treatments, which is generally less common for FFS Medicare.[17] Additionally, while beneficiaries in FFS Medicare can seek care from any provider that accepts Medicare, patients in MA plans have more limited provider networks.[18] While MA plans must comply with the network adequacy requirements under § 422.116, there may be insufficient guardrails to prevent MA plans from using networks to limit coverage for specialized therapies or treatment for chronic conditions; for example, by implementing additional credentialing requirements for providers to furnish specialty care.[19] Further, switching from MA to FFS Medicare can be cost-prohibitive, if not impossible, for beneficiaries. To offset the unlimited 20% coinsurance amount that enrollees must pay after meeting their deductible, beneficiaries can sign up for supplemental insurance, such as a Medigap policy.[20] However, Medigap insurers can deny or limit coverage to beneficiaries who transfer from MA plans, and few states prohibit Medigap policies from denying coverage to enrollees because of preexisting conditions.[21]

In response to this RFI, LUGPA asks that CMS prioritize collecting data on Medicare beneficiaries in MA plans who are seeking high-cost, complex treatments, including data related to prior authorization requests for such treatments. Additionally, we respectfully request that

[16] The Commonwealth Fund, *Medicare Advantage: A Policy Primer* (Jan. 31, 2024), available at: https://www.commonwealthfund.org/publications/explainer/2024/jan/medicare-advantage-policy-primer.

[17] *Id.*

[18] *Id.*

[19] 42 CFR § 422.116.

[20] Sarah Jane Tribble, *Older Americans Say They Feel Trapped in Medicare Advantage Plans*, Kaiser Health News (Jan. 5, 2024), available at: https://kffhealthnews.org/news/article/medicare-advantage-medigap-enrollment-trap-switch-preexisting-conditions/.

[21] *Id.*

CMS collect data on MA plans with additional credentialing requirements for in-network providers to administer specialty care and compare any such requirements to those required by FFS Medicare.

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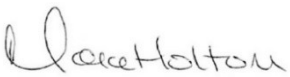
On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on this RFI. Please feel free to contact Dr. Mara Holton at 410.504.4004 or mholton@aaurology.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



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