



One Prince Street
Alexandria, VA 22314-3318
☎ 703.838.0033
✉ 703.548.1890

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Brooks-LaSure:

On behalf of the AMGA, I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, entitled "Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications."

Founded in 1950, AMGA represents more than 440 multispecialty medical groups and integrated delivery systems, representing approximately 177,000 physicians who care for one in three Americans. Our member medical groups work diligently to provide innovative, high-quality, cost-effective, patient-centered medical care. Our overarching legislative and regulatory goals revolve around advancing the shift from fee-for-service (FFS) payments to reimbursement based on the value of care provided.

AMGA is pleased to offer comments on the proposed rule for your consideration. Specifically, we are providing comments on the following:

- **Prior Authorization.** We note that prior authorization continues to serve as a costly barrier to patient care access, and we support stronger protections that more clearly streamline these processes and minimize adverse patient impacts. We applaud CMS' efforts to address prior authorization practices and support CMS' proposal to require Medicare Advantage (MA) plans to follow Medicare national coverage determinations (NCDs), local coverage determinations (LCDs), statutes, and regulations when making medical necessity decisions. We also support CMS' proposal to require plans to have a Utilization Management Committee.
- **Behavioral Health.** Access to behavioral health is critical to integrated care delivery, and we support CMS' proposals to expand network adequacy requirements and improve access to behavioral health services for enrollees.

- **Medication Therapy Management.** We encourage more active engagement of patients in their care delivery, and we support CMS' proposal to include additional requirements for Part D Medication Therapy Management (MTM) programs.
- **Part D and Generic Substitutions.** It is important to protect the critical role physicians play in ensuring that care is rendered within safe and efficacious standards. While supportive of generic substitutions, CMS should clarify its proposal to ensure providers will maintain the ability to prescribe brand-name treatments when clinically appropriate.
- **Medicare and Part D Marketing Reforms.** It is important that patients can make informed decisions about their insurance coverage, and we support CMS' proposals to protect MA and Part D enrollees and individuals shopping for Medicare coverage from confusing and misleading marketing practices.
- **Overpayment.** It is important that providers be afforded ample time to conduct overpayment investigations to determine both whether an overpayment actually occurred and the overpayment amount. We believe the existing reasonable diligence standard adequately addresses overpayment situations, and we oppose CMS' proposal regarding the identification of overpayments.

Our detailed comments are included below.

Prior Authorization

Recommendation: CMS should finalize its proposals to require MA plans to follow Medicare coverage policies, statutes, and regulations when making medical necessity decisions as well as to require MA plans make public the factors considered in internal coverage criteria and use current evidence in widely used treatment guidelines or clinical literature when developing these criteria.

CMS is proposing several changes to MA prior authorization policies to ensure MA enrollees have timely access to medically necessary care. AMGA is pleased that CMS is addressing concerns with prior authorization, both in this rule and separately in its Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies proposed rule.¹

Specifically, CMS is proposing to, among other things, require MA plans to follow Medicare national coverage determinations (NCDs) and local coverage determinations (LCDs), statutes, and regulations when making medical necessity decisions and establish a Utilization Management Committee to review policies annually to ensure consistency, and to specify that plans can only use prior authorization to confirm the presence of diagnoses or other clinical criteria that supports the medical necessity of an item or service.

As noted in previous comments, AMGA maintains the issues surrounding prior authorization can best be solved by eliminating it when possible. As we noted in comments earlier this year to the Office of the National Coordinator, regulators and stakeholders should implement an electronic

¹ 87 Fed. Reg. 76238

prior authorization process that automatically clears or waives prior authorization requirements, including for pharmaceuticals, for those providers who either are participating in a value-based model of care or have demonstrated they deliver high-quality care.

Our concerns with prior authorization are not limited to value-based care models, but also are applicable to Medicare Advantage. While CMS has acknowledged that MA plans may use prior authorization as a utilization management tool, AMGA believes prior authorization is a blunt instrument that ultimately increases providers' workload and costs while also contributing to access to care barriers for MA enrollees. Similar to value-based models, the incentives to over-utilize select procedures, tests, or medications are simply nonexistent for providers with risk-based Medicare Advantage contracts and prior authorization rules should reflect this reality.

Regarding its specific proposals, CMS would restrict the use of prior authorization for coordinated care plans to confirm the presence of a diagnosis. This proposal is in response to findings from the Department of Health and Human Services, Office of Inspector General (OIG) indicating that flaws in MA prior authorization resulted in inappropriate care denials.² However, AMGA does not understand the purpose of this proposal. MA plans should not need to re-verify or reconfirm a diagnosis, as providers will have supplied that information when ordering a particular test, medication, or procedure. A patient's diagnosis or condition is linked to a particular order, and despite CMS' goal of streamlining and simplifying the prior authorization process, using it to "confirm the presence of a diagnosis" appears to serve no purpose, other than to inadvertently delay care.

It is paramount that MA enrollees be afforded the same protections and benefits as Medicare Fee-for-Service beneficiaries. However, increasingly, MA prior authorization decisions are being substituted in place of a physician, who is best suited to understand a patient's unique care needs. We also note that prior authorization requests often are reviewed by clinicians outside of the specialty of the service being requested. This raises serious questions about the purported benefit of prior authorizations for timely and appropriate care delivery.

Prior authorizations and restrictive coverage policies remain significant barriers that contribute to inequitable care access, and we believe changes here would closely align with efforts to advance equity.

Accordingly, AMGA strongly supports CMS' proposal to require MA plans to follow Medicare coverage policies, statutes, and regulations when making medical necessity decisions. AMGA also supports CMS' proposal to make public the factors considered in internal coverage criteria and to use current evidence in widely used treatment guidelines or clinical literature when developing these criteria.

Further, AMGA agrees with CMS' proposal to require plans to establish a Utilization Management Committee, which would be led by a medical director. We note that providers who have contracts with the plan should be afforded access to any findings or determinations of this committee, as well as to provide input to inform medically reasonable and necessary care

² Grimm, CA. OIG. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. April 2022. <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>.

delivery.

Behavioral Health

Recommendation: CMS should finalize its proposals to improve access to behavioral health services for MA enrollees, and to improve network adequacy requirements to account for increased behavioral health specialties.

CMS is proposing several provisions to improve enrollee behavioral health access and to expand network adequacy requirements to include additional behavioral health specialty types. Specifically, CMS is proposing, among other things, to add Clinical Psychology Licensed Clinical Social Worker and Prescribers of Medication for Opioid Use Disorder as specialty types evaluated as part of the network adequacy reviews, as well as clarify that behavioral health services used to evaluate and stabilize an emergency medical condition are included in emergency medical services and are not subject to prior authorization.

AMGA strongly supports proposals to improve access to behavioral health services for MA enrollees and to improve network adequacy requirements to account for increased behavioral health specialties. Indeed, we are pleased that CMS recognizes the importance of enrollee access to behavioral health services in its proposal to explicitly include these services in the general access to service standards. AMGA also is pleased that CMS will include tele-behavior health in evaluating network adequacy.

We further agree that behavioral health services should not be subject to prior authorization when used to evaluate and stabilize a patient's emergency medical condition. We believe these proposals are a critical step in the goal to ensure behavioral health access and are in alignment with CMS' efforts to advance health equity.

Medication Therapy Management

Recommendation: CMS should finalize its proposal to add additional diseases to inform MTM program targeting criteria to promote consistent, equitable, and expanded access to MTM services.

CMS is proposing several new requirements for Part D sponsors related to Medication Therapy Management (MTM) programs. Specifically, CMS is proposing changes to the MTM targeting criteria by requiring Part D sponsors to include all core chronic diseases in their targeting criteria and adding HIV/AIDS for a total of 10 core chronic diseases.

Under current regulations, all Part D sponsors are required to have an MTM program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events, including adverse drug interactions. Part D sponsors are also required to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary.

AMGA supports CMS' proposal to add additional diseases to inform MTM program targeting criteria to promote consistent, equitable, and expanded access to MTM services. AMGA

members emphasize the importance of care coordination and support efforts to help patients manage their chronic diseases. Indeed, these patients often have different care needs, and it is critical to promote positive therapeutic outcomes and to minimize adverse risks for these patient populations.

AMGA supports the improvement of the Part D MTM, as it will help patients better understand their condition, share in decision making, follow a care plan, and monitor and manage their signs and symptoms. This is an important step in promoting positive care outcomes.

Part D and Generic Substitutions

Recommendation: CMS should modify its proposal regarding immediate formulary substitutions. AMGA members are accustomed to generic substitutions. However, CMS should clarify that providers will maintain the ability to prescribe a brand-name drug or biological product. CMS should work closely with stakeholders to develop a policy that would facilitate collaboration among Part D plans, providers, pharmacists and patients to discuss medication changes to ensure patient safety.

CMS is proposing changes to provide Part D with more tools to manage drug costs and increase formulary flexibility for certain types of drugs. The proposed rule would permit Part D sponsors to immediately substitute a new interchangeable biological product for its corresponding reference product, a new unbranded biological product for its corresponding brand-name biological product, and a new authorized generic for its corresponding brand-name equivalent.

Currently, Part D sponsors are allowed to immediately remove a brand name drug from the formulary and substitute its newly released generic equivalent. The proposal would be consistent with this current flexibility, and specific formulary changes would be subject to CMS approval and 30 days advance notice to affected beneficiaries. However, under this proposal, immediate formulary substitutions do not require advance notice and the Part D plan can provide information on the specific changes, including direct notice to affected beneficiaries after they take place. Plans would be able to make these changes at any time including in advance of the plan year. In addition, plans would not need to provide a transition supply of the substituted drug.

While supportive of generic substitutions as a concept, it is important providers and patients be informed of any changes to a prescription coverage to appropriately inform clinical decision-making. While generic substitution is generally safe and effective, it may not be appropriate in all cases. In addition, transition supplies may be warranted in these circumstances. Part D plans should work closely with providers and patients with any changes to medications to ensure patient safety. While AMGA does not oppose CMS' proposal, CMS and Part D plans should also ensure that providers maintain the ability to prescribe name-brand products when medically necessary.

Medicare and Part D Marketing Reforms

Recommendation: CMS should finalize its proposals to protect individuals shopping for MA and Part D coverage from confusing and misleading marketing practices.

CMS is proposing policies to protect people shopping for MA and Part D coverage from confusing and misleading marketing. Specifically, CMS is proposing to require plans to notify enrollees annually of their ability to opt out of phone calls regarding MA and Part D plan business and to require agents to explain the effect of an enrollee's enrollment choice on their current coverage.

Simplifying plan comparisons is an essential step in ensuring that beneficiaries can make informed decisions about their healthcare coverage.

AMGA recommends that CMS finalize its proposal, which will help address beneficiary confusion and ensure they make informed decisions on their Medicare Advantage or Part D coverage.

Overpayment

Recommendation: CMS should not finalize its proposal to amend regulations concerning the standard for an identified overpayment for Medicare Parts A, B, C, and D.

CMS is proposing changes to existing regulations concerning the standard for an identified overpayment for Medicare Parts A, B, C, and D. Specifically, under the proposed rule, an MA organization, Part D sponsor, provider or supplier is determined to have identified an overpayment if it has actual knowledge of the existence of the overpayment, or acts in reckless disregard or deliberate ignorance of the overpayment, consistent with the meaning given to the terms 'knowing' and 'knowingly' in the False Claims Act.³ Therefore, a provider would be required to report and return overpayments within 60 days of the provider having actual knowledge or being in reckless disregard or deliberate ignorance of the existence of the overpayment. This would replace the current regulation, which allows providers time to conduct "reasonable diligence" before determining an overpayment.

Currently, providers and suppliers who identify Part A and/or Part B overpayments may perform an investigation to determine the amount of overpayment before notifying the government and returning the overpayment. The provider then has 60 days from the time of notification to return the overpayment. The proposed rule bumps up this timeline by setting the 60-day clock from the time the provider has actual knowledge, or reckless disregard or deliberate ignorance, of the overpayment. This acceleration of the timeline from knowledge to returned overpayment disallows providers from performing due diligence to investigate and verify the overpayment amount.

Accordingly, AMGA opposes this proposal. While we recognize the necessity of holding those accountable to return overpayments in a timely manner, we believe the existing reasonable diligence standard adequately accomplishes this objective. We also note there will be significant challenges and confusion in validating the amount of an overpayment if ample time is not provided to determine whether an actual overpayment actually occurred, and if so, the proper overpayment amount.

Conclusion

We thank you for your consideration of our comments. Should you have questions, please do not

³ See 31 U.S.C. 3729(b)(1)

hesitate to contact AMGA's Darryl M. Drevna, senior director of regulatory affairs, at 703.838.0033 ext. 339 or at ddrevna@amga.org.

Sincerely,

A handwritten signature in cursive script that reads "Jerry Penso".

Jerry Penso, M.D., M.B.A.
President and Chief Executive Officer, AMGA