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August 31, 2022

Via Electronic Submission Only
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-4203-NC
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Request for Information on Medicare (CMS-4203-NC)

Dear Administrator Brooks-LaSure:

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to provide comments to CMS on the Request for Information (RFI) on Medicare regarding ways to strengthen the Medicare Advantage (MA) program to align with the Vision for Medicare and CMS' Strategic Pillars. We commend CMS for creating opportunities for engagement as the Agency works to develop and implement new policy and process regarding the MA program. We note the 30-day comment period on the RFI is challenging, given the scope of the information requested, and we hope this RFI represents the first of multiple opportunities for stakeholder feedback on these critical issues.

AdvaMed member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings and to advancing health equity.

Medicare Advantage continues to grow at an accelerated pace. The Kaiser Family Foundation (KFF) reports that enrollment in MA has doubled over the past decade.[1] In 2020, 39% of all Medicare beneficiaries were enrolled in MA plans and the Congressional Budget Office projects that that share will rise to about 51% by 2030.[2] MA plans play an increasingly vital role in ensuring Medicare beneficiaries have access to medically necessary covered services. Thus, it is imperative CMS ensure the services provided by MA plans appropriately align with traditional Medicare coverage. Moreover, as MA plans continue and expand independent coverage systems and processes, such as prior authorization (PA) programs, CMS should consider ways to prevent inappropriate denials of services resulting from the use of these programs and ensure the programs are advancing health equity.

Below, AdvaMed offers comments and recommendations on Sections A and B of the RFI focused on health equity and coverage and care.

Overarching Recommendation:

- **CMS should ensure that MA plans advance health equity and are not curtailing access to products/treatments available under traditional Medicare.**

A. Advance Health Equity

Health Equity is a pivotal component of the CMS strategic pillars. AdvaMed strongly supports efforts to ensure that patients who enroll in MA plans have access to equitable care. As a medical device trade association, we are sensitive to the impact inadequate health care has on patient and population health. Ensuring access to appropriate services and procedures by all of the patients who require them is critical in improving health outcomes for all patients. This is especially imperative in the context of MA plans which have high rates of enrollment among Medicare patients who are people of color, women, as well as those who have lower incomes.[3]

Since their inception MA plans have become an attractive alternative for Medicare patients who are seeking additional services that are not part of traditional Medicare plans. While these plans are required to cover all Medicare approved services and procedures they are not required to

[1] Freed M, Damico A, and Neuman T. A Dozen Facts About Medicare Advantage in 2020. Kaiser Family Foundation website. January 13, 2021. Accessed August 10, 2022. https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/

[2] *Id.*

[3] Alliance of Community Health Plans. FACT SHEET — Medicare Advantage: Serving a Diverse, Rapidly Growing Population. August 18, 2022. https://achp.org/ma-serving-a-diverse-population/#:~:text=Medicare%20Advantage%20(MA)%20serves%20diverse,incomes%20of%20less%20than%20%2430%2C000

cover all of the alternatives for rendering these services. This could result in inequitable health care being offered by these plans depending upon the nature of the patient concern and the needed treatment.

Achieving the best possible health outcomes is premised upon patients being evaluated to assess their individual needs with regards to the most appropriate care and treatment to address their condition. An important part of this assessment is giving care providers the flexibility to determine, in consultation with the patient, the most appropriate course of treatment. AdvaMed recommends that, to promote health equity, MA plans be required to adopt more flexible processes, in instances where the benefits offered by the plan do not align with the care needed to produce the best patient outcome, to evaluate alternative care options for enrolled patients based on their caregivers' recommendations. Additionally, a fast-track review process for determining solutions and alternative paths to treatment, such as in-home care, for diseases prevalent in underserved communities (e.g., sickle cell and kidney disease) and for patient populations with a history of disparate outcomes may be helpful in advancing health equity objectives.

In this RFI CMS poses several questions to stakeholders regarding its ability to enhance health equity for patients enrolled in MA plans. We would like to offer the following feedback:

1.*What steps should CMS take to better ensure that all Medicare Advantage enrollees receive the care they need?*

> This goal can be advanced through improving the collection, reliability, and validity of sociodemographic factors data. CMS should reevaluate the current methods for collecting sociodemographic factors—including but not limited to, definitions of race and ethnicity, ability to select more than one race and ethnicity, and options for sex and gender. The agency should also recognize that these sociodemographic factors can be a proxy for other underlying disparities (e.g., access to care, infrastructure, systemic and institutional racism, etc.).
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> The agency could also consider increasing requirements or incentives for reporting sociodemographic factors for all beneficiaries. To facilitate improved data collection, CMS could incentivize payers/providers to collect qualitative patient-reported experiences of care to complement quantitative data collection and measure quantity and quality of sociodemographic data collected to adjust incentives, over time, as appropriate. Providing transparent feedback and use cases, to beneficiaries regarding why collecting this information is important and how it can ultimately improve patient outcomes, will help engage MA patients in the process.
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> Another critical aspect of insuring health equity for MA plan enrollees hinges around their access to technologies, services, and procedures subject to plan guidelines and limitations. To better understand the impact of these requirements on beneficiaries, CMS should

conduct, support, and/or consider updated research to evaluate current MA plan guidelines. This research could start with an evaluation of health disparities in vulnerable or underserved populations to understand gaps in current care associated with the diagnosis and treatment of prevalent disease states, collection and review of patient-reported outcomes highlighting quality of care received and areas to improve, and evaluation of the effectiveness of clinical practice and diagnostic standards/threshold values that serve as the standard of care for all patients.

CMS could also evaluate analytic methods used for optimizing care and healthcare operations to ensure stratification by sociodemographic factors to provide transparency on model performance for different subpopulations—to assess for underlying biases and to understand impact on vulnerable or underserved populations. The agency should also encourage reporting of complete data (including sociodemographic factors) for any information used in generating algorithms and limiting the use of algorithms when data used to develop the model is incomplete—to reduce the likelihood of unintentional harm to beneficiaries (e.g., reduced access to care).

2.*What are examples of policies, programs, and innovations that can advance health equity in MA? How could CMS support the development and/or expansion of these efforts, and what data could better inform this work?*

Effectively advancing health equity is dependent upon an awareness of the problem. CMS can facilitate increased and/or improved awareness by supporting educational programs for health providers/payers that raise awareness of how health disparities impact patient care and show how to identify and mitigate unconscious biases. Similarly, the Agency can undertake initiatives to inform beneficiaries of why collecting sociodemographic information is important and how it can ultimately improve patient experiences and outcomes. Additionally, educational programs that improve beneficiaries understanding and navigation of the healthcare system, including information on how to access care coordinators and community advocates, could be helpful. MA plan beneficiaries could benefit from the provision of supportive care programs that promote access to care coordinators and community advocates to aid in navigating their care management. MA plan enrollees could also benefit from wellness and nutrition assistance programs which are instrumental in improving food insecurities and promoting preventive and routine healthcare.

Digital health solutions hold the potential of advancing access and delivery of equitable health to MA enrollees. Incentivizing health providers/payers to use digital health solutions, especially in rural communities that may struggle with accessing in-person care and for lower income enrollees who may have transportation and other cost concerns, can significantly impact outcomes. Additionally, expanding coverage and reimbursement for

telehealth services can help to avoid increasing disparities in access to digital health solutions by MA plan patients.

As CMS continues to contemplate ways to advance equity in MA plans the agency should engage multiple stakeholders, including beneficiaries, when designing policies, programs, and innovations that address health disparities. Needs assessments and ongoing evaluation of program efficacy should also be considered throughout the design and implementation process.

B. Expand Access: Coverage and Care

10. How do MA plans use utilization management techniques, such as prior authorization? What approaches do MA plans use to exempt certain clinicians or items and services from prior authorization requirements? What steps could CMS take to ensure utilization management does not adversely affect enrollees' access to medically necessary care?

In April 2022, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) released a report on MA plan denials of prior authorization (PA) requests.[4] Prior to the report, OIG's annual audits of MA plans showed widespread and persistent problems associated with inappropriate denials of services and payment. For the report, OIG reviewed a sample of 250 denials of PA requests by 15 of the largest MA plans. Key findings from this study showed 13% of PA denials were for service requests that met Medicare coverage rules, and 18% of payment denials were for claims that met the Medicare and MA billing rules. As noted by OIG, "[d]enying requests that meet Medicare coverage rules may prevent or delay beneficiaries from receiving medically necessary care and can burden providers."

MA plans must follow Medicare coverage rules to provide beneficiaries with all the basic benefits covered under Medicare (although they may also offer supplemental benefits). These rules are specified in Medicare regulations[5], as well as other places including national coverage determinations (NCDs), local coverage determinations (LCDs), and the Medicare Managed Care Manual (MMCM). Chapter 4, Section 160 of the MMCM provides MA plans with guidance on how they may utilize pre-service organization

[4] Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care. U.S. Health and Human Services Office of Inspector General website. April 2022. Accessed August 10, 2022. https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf
[5] Medicare Advantage Program 42 CFR § 422.101 (June 29, 2020)

determinations (e.g., prior authorizations).[6] Additionally, Section 40.1 of the Medicare Managed Care and Part D Appeals Guidance provides additional guidance on categories of decisions that MA plans may institute.[7] However, such guidance is difficult to find and often too general. More specificity and clearer guidance and parameters for MA plans would go a long way to ensure that MA plans are not placing inappropriate barriers to necessary, life-saving care.

AdvaMed members, their customers, and the patients they serve have experienced significant frustrations with the MA program where plans, often through PA programs, curtail or deny access to patient management products or treatments that are available under traditional Medicare under the same or similar medical circumstances. While MA plans may implement additional coverage requirements if the additional requirements do not violate the requirements in the relevant NCD or LCD, it is important to note the majority of services within the traditional Medicare system are fee-for-service and reside ***outside*** of an existing LCD or NCD. The above-referenced OIG report showed MA plans can still deny service if an existing coverage policy is in place; however, our members report denials occurring around services where no NCD or LCD exist are the predominant issue and are more difficult to navigate in getting that decision reversed or corrected. In these instances, it appears MA plans default to commercial medical policies, which often are more restrictive than coverage under traditional Medicare but identifying that in the absence of an existing LCD or NCD is very difficult. This is very challenging for Medicare beneficiaries to understand as there is little to no transparency into this process; and as a result, these beneficiaries are encountering barriers to access they would not face under traditional Medicare.

Similarly, we are aware of MA plan enrollees experiencing barriers to participation in investigational device exemption (IDE) trials, despite the requirement that MA plans ensure enrollees "are free to participate in any qualifying clinical trial that is open to beneficiaries in original Medicare." While CMS states that MA plans "are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area,"

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[6] "*Organization Determinations: An enrollee, or a provider acting on behalf of the enrollee, always has the right to request a pre-service organization determination if there is a question as to whether an item or service will be covered by the plan. If the plan denies an enrollee's (or his/her treating provider's) request for coverage as part of the organization determination process, the plan must provide the enrollee (and provider, as appropriate) with the standardized denial notice (Notice of Denial of Medical Coverage (or Payment)/CMS-10003).*"

[7] Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Centers for Medicare and Medicaid Services website. Accessed August 10, 2022. https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf

along with payment for routine care items and services in CMS-approved Category A and Category B IDE studies and CMS-approved Category B devices, we understand some enrollees are encountering barriers to obtaining coverage for participation in these trials. We encourage CMS to ensure this policy is enforced, and that MA plans impose no coverage restrictions or prior authorization requirements pertaining to IDE trials that are not imposed by Medicare Administrative Contractors (MACs) in the MA plan's service area.

Additionally, the prior authorization process can cause unnecessary delays and additional administrative burdens for MA plan enrollees when required by MA plans. Moreover, if the prior authorization requests are administered incorrectly or unnecessarily denied for any reason this may cause further delays to the healthcare treatment, which can have dire implications for the patient and result in burdens to the healthcare provider. Using the example of IDE clinical trials with Category A and B designation, there is designated coverage by traditional Medicare, yet MA plans are requiring prior authorizations. This is an administrative burden for healthcare providers and a delay in care for the patient.

To address these persistent concerns about beneficiary access to care, we recommend CMS adopt policies to explicitly ensure MA plan enrollees are given the same access to medical therapies as traditional Medicare beneficiaries, both in terms of Medicare coverage standards and prior authorization policies. Specifically, we recommend CMS require MA plans to cover medical items and services if they are available to traditional Medicare beneficiaries under the terms of an LCD, NCD, or through individual consideration by the Medicare Administrative Contractors (MACs) in the MA plan's service area on a claim-by-claim basis. Further, AdvaMed recommends CMS consider whether MA plans should even require prior authorization in situations when there is a defined CMS NCD and/or LCD coverage policy in place. In situations where prior authorizations are required, we urge CMS to require and monitor the appropriate use and timely application of treatment and authorization guidelines.

11. What data, whether currently collected by CMS or not, may be most meaningful for enrollees, clinicians, and/or MA plans regarding the applications of specific prior authorization and utilization management techniques? How could MA plans align on data for prior authorization and other utilization management techniques to reduce provider burden and increase efficiency?

AdvaMed's recommendations strongly align with the April 2022 HHS OIG report's recommendations. We are encouraged to see that within the report CMS agrees with all of

the OIG's recommendations. Below, we provide additional information for CMS to consider as it works to institute the OIG's recommendations.

1. *Issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews.*

   AdvaMed supports this first recommendation made by the HHS OIG in the April 2022 report. As was highlighted earlier in this document, our members report that a lack of clear guidance as a key contributor to the discrepancies between MA plans and traditional Medicare coverage. Specifically, guidance from CMS on how MA plans should align with coverage under traditional plans in the absence of an NCD or LCD should be a priority, as items and services covered outside of these determinations represent the majority of services covered under traditional Medicare. We also agree that new guidance should work to clarify language within the MMCM manual when it states that coverage criteria by MA plans must not be "more restrictive" than Medicare coverage rules.

   AdvaMed also believes improvements to the CMS NCD process could assist MA plans in aligning coverage with traditional Medicare. The current NCD process can take six to nine months, or longer, after CMS initiates an NCD, and CMS typically issues only a handful of NCDs each year. A related issue is the lack of transparency surrounding CMS' methods for managing NCD requests, prioritizing topics and the provision of information to the public regarding the waiting list. We often hear from our members that a formal NCD request was submitted to CMS, but because there is no specified timeline for CMS to respond to such requests or to provide information regarding the waiting list, requestors have no visibility into the process or timeline for action on their requests. Efforts to improve and streamline the NCD process, including CMS' current efforts under Traditional Coverage of Emerging Technologies (TCET), could indirectly improve this issue by increasing the number of NCDs active and available, making it easier for MA plans to align coverage with traditional Medicare.

2. *Update its audit protocols to address the issues identified in this report, such as MAO use of clinical criteria, and/or examine particular service types*

   The OIG report notes there are several tools currently in place that CMS uses to oversee the performance of MA plans, including a yearly audit to measure MA plans' compliance with their CMS contract. AdvaMed believes a bolstering of the audit process and a continued review of MA claims data for trends would best inform future new guidance and audit parameters by CMS. Additionally, a deeper analysis

could aid CMS in identifying issues with MA plans earlier and more often. Such analysis also could identify any issue trends that would benefit from clearer guidance by CMS within the MMCM. Below we offer some specific recommendations for additional audits and data analysis.

i. **Comparison of physician utilization of services between traditional Medicare and MA plans:** This analysis would allow CMS to understand incidence among both the MA plans and traditional Medicare and determine any additional trends, such as decreased utilization of services under MA plans, that should be considered for audits going forward.

ii. **Longitudinal Analysis:** AdvaMed believes a thorough analysis over time of the average time from the diagnosis to prescription to service in traditional Medicare and across MA plans would help identify potential issues with processing of claims within MA plans. Additionally, an assessment of claims processed versus claims denied would allow CMS to identify ongoing and new issues with certain covered services.

iii. **Comparison of denials for services covered under existing Medicare coverage determinations (i.e., NCD, LCD) and denials where no formal coverage determination exists in MA plans:** Our members report that when MA plans deny claims for services, there is often not a clear reason as to why the service was denied, especially for services not covered under an NCD or LCD. Performing this analysis may help identify MA plan denial trends and inform process improvements going forward.

3. *Direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors.*

   We agree CMS should direct MA plans to take additional steps within their own systems to address these problems. MA plans should also report vulnerabilities found in their system to CMS to help inform processes by other MA plans. CMS might consider implementing penalties or other incentives to encourage MA plans to take such steps.

Conclusion

AdvaMed appreciates the ability to share these comments and looks forward to continuing to work with CMS and other stakeholders to advance equity and to expand access through improved coverage and care in MA plans and other programs. We would be pleased to answer any questions regarding these comments or AdvaMed's work to advance health equity and to improve the prior authorization process. Please feel free to contact Tara Burke (tburke@advamed.org) with any

questions regarding our prior authorization recommendations or me at (ddorsey@advamed.org) regarding the health equity recommendations, if we can be of further assistance.

Sincerely,

DeChane L. Dorsey, Esq.
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