May 29, 2024

Via Electronic Submission

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
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 [CMS–4207–NC]

Dear Administrator Brooks-LaSure,

On behalf of the Medical Device Manufacturers Association (MDMA), below please find comments in response to the Request for Information (RFI) on Medicare Advantage (MA) Data. MDMA is a national trade association that provides educational and advocacy assistance to hundreds of innovative companies in the field of medical technology. Our members, the majority of which are small to mid-sized medical device companies, have a strong record of delivering breakthrough therapies to treat chronic diseases and life-threatening conditions while lowering the cost of care. MDMA’s mission is to ensure that patients have timely access to the latest advancements of safe and effective medical technologies that improve health outcomes.

MDMA appreciates the opportunity to provide input to CMS on ways to increase transparency and improve the MA program for Medicare beneficiaries.

Prior Authorization & Utilization Management Practices
MDMA believes that inappropriate and unnecessary prior authorization requirements restrict access for beneficiaries to medically necessary procedures and add undue administrative and cost burden to providers. Those concerns were validated in a 2022 study by the HHS Office of the Inspector General that identified inappropriate delays and denials of medically necessary care that met Medicare coverage rules. MDMA also believes that there are significant questions relating to whether prior authorization plays a role in creating and sustaining disparities in health care access and treatment for beneficiaries of color and those living in underserved communities.

Research into these questions is unfortunately quite limited; however, a 2019 white paper published by the Association of Black Cardiologists “hypothesized that lower resource levels at cardiology practices with a majority of patients from underserved and minority populations may pose a unique barrier to responding to [prior authorization] needs for these patients, further fostering existing treatment disparities.”

MDMA appreciates the actions that CMS has taken in the MA policy rules\(^4\) for contract years 2024 and 2025 and the final rule\(^5\) related to interoperability and prior authorization released earlier this year. Those actions should help alleviate some of the administrative burden of prior authorization requirements for providers and improve access to care for beneficiaries. However, we are concerned about the lack of clear enforcement mechanisms to ensure MA and other health plans comply with the new requirements. As a result, we recommend CMS strengthen reporting requirements for MA plans by requiring annual submission of information set forth in 42 CFR 422.122(c) directly to CMS (in addition to public posting on plan websites)—as set forth in the proposed “Improving Seniors Timely Access to Care Act”\(^6\)—and require MA metrics to be reported on an aggregate, plan and individual service basis.

MDMA also believes that the collection of additional information related to MA plan utilization management practices would be helpful to beneficiaries, other stakeholders, Congress and CMS. Specifically, we recommend that CMS require MA plans to:

1. Identify third-party vendors used to review prior authorization requests and conduct other utilization management (UM) activities, along with a description of the scope of responsibilities;
2. Provide information regarding any artificial intelligence (AI) algorithms used for prior authorization denials or similar medical necessity reviews;
3. Report to CMS whether they impose prior authorization or other requirements for specific items or services covered under the CMS clinical trial policies or Coverage with Evidence Development (CED) determinations; and
4. Report annually on specific actions taken at the plan level to comply with the requirements of 42 CFR 422.137 relating to the establishment and responsibilities of a Utilization Management Committee.


\(^5\) 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, 89 Fed. Reg. 8,758 (Feb. 8, 2024).

**Provider Directories & Network Adequacy**
MDMA believes that improvements in MA-related data collection can and should be made with respect to MA plans’ network adequacy in terms of critical therapies for Medicare beneficiaries. Specifically, MDMA recommends CMS identify a range of critical items and services covered under National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) and require MA plans to report on network adequacy in relation to access to those important therapies.

Additionally, CMS should ensure that existing directories are accurate and updated regularly as enrollees increasingly use these directories to choose their providers, and inaccuracies will delay access to care.

**Supplemental Benefits**
MDMA strongly supports recommendations from stakeholders for CMS to collect and release more MA data on supplemental benefit costs and utilization. MDMA shares the concerns expressed by many policy experts that MA plans use supplemental benefits to achieve marketing and enrollment objectives rather than promote the health and well-being of enrollees, that those supplemental benefits are often designed to attract younger and healthier beneficiaries viewed as less likely to require traditional items and services, and that the cost of providing such supplemental benefits is derived in part from policies and practices designed to limit utilization of traditional benefits. Additional data collection would increase the ability of CMS and other policy experts to evaluate whether new policies are needed to address those concerns.

**Payments for Innovative Technologies**
MDMA encourages CMS to collect and analyze data from MA plans relating to payment rates for new technology procedures that are eligible for additional fee-for-service (FFS) payments, such as New Technology Add-On Payments (NTAP) for hospital inpatient procedures and Transition Pass-Through Payment for procedures performed in a hospital outpatient setting or ambulatory surgery center. We believe those incremental FFS payments are included in calculating traditional Medicare spending to determine CMS payments to MA plans; however, to the extent that MA plan payments to hospitals for such procedures is tied solely to the related MS-DRG or APC base payment in FFS, MA plans are receiving a windfall and providers may be receiving payment that is inadequate to cover the cost of the service.

* * *

If we can provide any additional information, please contact Daniel Waldmann, Executive Vice President, Health Policy & Reimbursement, at dwaldmann@medicaldevices.org or (202) 841-9953.

Sincerely,

Mark Leahy
President & CEO
Medical Device Manufacturers Association