

Sound Policy. Quality Care.

May 20, 2024

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

Submitted electronically via Regulations.gov

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

Dear Administrator Brooks-LaSure,

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians across 16 specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care by advancing sound health policy. Our organizations write to share collective insights and recommendations in response to CMS's Request for Information on Medicare Advantage (MA) data, emphasizing our commitment toward ensuring beneficiaries enrolled in MA plans have access to high-quality, specialized care. With the increasing number of beneficiaries choosing MA plans, it is paramount that CMS improve its policies to ensure the health needs of this growing population are being met, particularly where specialty medicine is concerned. As such, CMS must improve the availability of data and information for beneficiaries and the public to evaluate MA plans.

Beneficiary Access to Care

The Alliance remains concerned about access to specialty care for beneficiaries enrolled in MA plans. As we have shared previously, MA plan networks are woefully inadequate, in part because not all specialty and subspecialty providers are "counted" in CMS' quantitative standards. Additionally, MA provider directories remain largely inaccurate, as evidenced by multiple agency studies, including those by CMS, which is exacerbated by CMS' failure to strictly enforce its requirements or impose financial and other penalties.

We have suggested several regulatory reforms that would mitigate some of these challenges, as discussed in detail below, and urge CMS to adopt these in the next rulemaking cycle (i.e., 2026). *These*

www.specialtydocs.org

info@specialtydocs.org

American Academy of Facial Plastic and Reconstructive Surgery • American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons • American College of Mohs Surgery • American College of Osteopathic Surgeons
American Gastroenterological Association • American Society for Dermatologic Surgery Association

American Society of Cataract & Refractive Surgery • American Society of Echocardiography • American Society of Plastic Surgeons
American Society of Retina Specialists • American Urological Association • Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons • National Association of Spine Specialists • Society of Interventional Radiology

recommendations all share the goal of improving the availability of data and information for beneficiaries and the public to evaluate MA plans.

Update the "specialty types" that plans must ensure meet CMS' time/distance standards so that additional specialties and subspecialties are considered. CMS holds MA plans accountable for 29 specialty types in its network adequacy standards, yet there are many more recognized specialty and subspecialty types. For example, the American Board of Medical Specialties (ABMS) oversees 24 Member Boards that represent 40 medical specialties and 89 subspecialties, while the Association of American Medical Colleges (AAMC) recognizes more than 160 specialties and subspecialties in the United States, including many recognized by ABMS-equivalent certifying boards. By not considering the full range of specialists and subspecialists in its network adequacy standards, CMS has allowed plans to avoid responsibility for true network adequacy.

Most MA enrollees do not realize the limitations of their plan's provider network until they are faced with a critical need for specialty medical care. In most cases, beneficiaries enrolling in a MA plan check to see if their current physicians are in the network (e.g., their primary care physician and other specialists they routinely see). However, through the course of the plan year, it is not uncommon for other health issues to arise. We have heard multiple anecdotes where enrollees have signed up for a plan, are diagnosed with a new health condition – for example, a skin cancer on the forehead – and discover there is not a single Micrographic Dermatologic Surgeon in the plan's network.

Perhaps more frustrating is that CMS recognizes the importance of a robust MA network but has focused its network improvements on specialists who deliver care that aligns with the Administration's policy priorities, rather than other pressing health care needs of enrollees. For example, CMS added network adequacy evaluation standards for a new facility-specialty provider category — Outpatient Behavioral Health — that includes a range of behavioral health providers (e.g., marriage and family therapists, mental health counselors, Opioid Treatment Program (OTP) providers, Community Mental Health Centers, addiction medicine physicians, and other providers, like nurse practitioners (NPs), physician assistants (PAs), and Clinical Nurse Specialists (CNSs), who regularly furnish addiction medicine and behavioral health counseling or therapy services covered by Medicare). While access to these providers is important, we note that CMS has reported high rates of heart disease, arthritis, and diabetes, but has not ensured robust enrollee access to the specialists that are most qualified to diagnose, treat and manage these conditions.

Enrollees deserve access to a robust range of specialty and subspecialty physician types, similar to their counterparts in traditional Medicare. Adding additional specialties will also facilitate a more robust provider directory, which beneficiaries use to make enrollment decisions. *CMS should include additional "specialty types" to the list that plans must ensure meet CMS' time/distance standards.*

Revise the time/distance standards that better reflect beneficiary access to care needs. CMS' current time/distance standards are inadequate for some specialty types, particularly for those specialties that face critical workforce shortages and that treat diseases currently at epidemic levels or increasingly common in the Medicare population.

As an example, the time/distance standards for rheumatology are insufficient and have resulted in inadequate coverage, increased costs, and delays in care for some enrollees. In Florida, one MA plan eliminated more than two thirds of all rheumatologists from its network for "no cause," leaving beneficiaries in one county – the largest in the state – with only nine rheumatologists out of the available forty-two, all of whom were in the plan prior to 2024. At the request of one terminated

physician, CMS conducted a network adequacy review and found that the plan's network was adequate based on its current standards, but acknowledged the termination was significant.

We are concerned that CMS' time/distance standards are inconsistent with enrollee needs, where chronic health conditions are on the rise and the specialty workforce in becoming more limited. **CMS** should reevaluate and revise the time/distance standards based on beneficiary needs now, and what is projected for the future.

Add appointment wait time standards for all specialties. Wait time standards have been adopted for primary care and behavioral health, despite increasing reports of patients being unable to access other specialty medical providers in a timely fashion. Considering CMS has finalized wait times for specialty care providers as part of its regulations for Affordable Care Act (ACA) plans and Medicaid Managed Care Organizations, it is unclear why MA would be any different. In fact, in 2022, MA plans' enrollee risk scores were about 18 percent higher than those for enrollees in traditional fee-for-service Medicare, suggesting their populations suffer from multiple chronic, comorbid conditions (with Medicare paying a correspondingly high premium as a result of these risk scores). It thus stands to reason that improved access to specialists that are best suited to manage these conditions would be in the best interest of the plan and its enrollees. *CMS should add wait times for specialists and subspecialists*.

Require transparency in value metrics used for network management. MA plans routinely evaluate the providers in their network based on quality and cost metrics. Based on these evaluations, plans "tier" physicians relative to their "peers," or in some cases, terminate physicians from plan networks. The quality and cost metrics used by MA plans are not transparent; physicians usually learn they have been evaluated for tiering or termination after the fact and without recourse.

CMS should require plans to publicize the value metrics and underlying algorithms they use for network management purposes. Transparency would allow physicians to know and understand the standards by which they are being evaluated, which is a prerequisite for improvement. Additionally, transparency would enable professional societies and other public stakeholders to identify any issues in the measures' logic or methodology and recommend improvements.

CMS should also require MA plans to provide physicians with detailed feedback about the plan's evaluation of their quality and cost, along with an opportunity to appeal negative determinations and rejoin the plan's network.

Enforce requirements that plans maintain accurate, real-time provider directories that include specialty and subspecialty designations. As noted above, MA provider directories remain largely inaccurate based on agency reports, watchdog agency studies, and anecdotal reports. Inaccurate directories create challenges for beneficiaries in evaluating whether a plan meets their current healthcare needs or those they may have in the future.

The incentives for plans to maintain accurate, real-time provider directories are limited. *CMS must* strictly enforce its provider directory requirements and impose financial and other penalties, including termination, when these requirements are not met. *CMS* should also publicly report which plans have not met provider directory requirements and the penalty(ies) imposed.

Additional suggestions to improve access to specialists in MA networks are discussed in the <u>Quality</u> <u>Measures</u> section of this response.

Utilization Management

Utilization management practices, particularly prior authorization and step therapy, pose significant barriers to timely patient care. Specialty physicians frequently report delays in treatment initiation due to these bureaucratic hurdles, which put beneficiaries' health at risk.

We appreciate CMS' recently finalized policies to address several challenges associated with prior authorizations, including those described in the CY 2024 MAPD final rule regarding medical necessity reviews. However, CMS has yet to act on certain recommendations from the Department of Health and Human Services (HHS) Office of Inspector General (OIG), as discussed in their April 2022 report, including the following:

- CMS should direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors.
- CMS should 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.

Action on these recommendations are urgently needed based on the OIG's findings that:

- "...among the prior authorization requests that MAOs denied, 13 percent met Medicare coverage rules; in other words, these services likely would have been approved for these beneficiaries under original Medicare (also known as Medicare fee-for-service)," which were attributed to MAOs use of "clinical criteria that are not contained in Medicare coverage rules" and "based on internal MAO clinical criteria that go beyond Medicare coverage rules," and
- "...among the payment requests that MAOs denied, 18 percent of the requests met Medicare coverage rules and MAO billing rules," which were "caused by human error during manual claims processing reviews (e.g., overlooking a document) and system processing errors (e.g., the MAO's system was not programmed or updated correctly)."

Further, the agency did not ensure its requirements applied to medications – either pharmacy or medical benefit. *CMS must equally apply its prior authorization policies and public reporting requirements to all medications.*

We also remain concerned about CMS' step therapy policies as described in its 2018 step therapy memo. Step therapy requires patients to first try and fail to achieve desired outcomes with less expensive therapies before they can access therapies that are initially prescribed by their physicians. This "fail first" approach can lead to several critical issues, including delays in treatment, increased health risks, and additional burden on patients and their physicians. In addition, navigating these protocols are complex and frustrating, leading to more delays. Beneficiary access to therapies should not be hindered by arbitrary polices that do not factor in their unique clinical factors. *CMS should withdraw its 2018 step therapy memo.*

Finally, we believe there are additional metrics that CMS should adopt to better understand the impact of and improve its policies associated with step therapy by MA plans. Specifically, we urge CMS to collect and publicly report on the following:

- The timeframe from when the original medication(s) was first prescribed to when the original medication was approved (in months);
- The number and frequency of patient-physician encounters during the aforementioned timeframe, and total out-of-pocket cost sharing for each visit;
- The number of alternative medications required before the original medication was approved, including the length of authorization for each alternative medication (in days);

- The total out-of-pocket costs for each alternative medication required before the original medication was approved;
- The total out-of-pocket cost for the original medication prescribed;
- The number and rate of enrollees abandoning therapy;
- The number and rate of appeals associated with step therapy;
- The number and rate of appeals that resulted in an enrollee accessing the original medication prescribed before completing the step therapy protocol; and
- Clinical characteristics of patients among each disease state/health condition where step therapy is required, including diagnosis codes and social determinants of health as collected by the MA plan.

Additional suggestions to improve utilization management in MA are discussed in the <u>Quality Measures</u> section of this response.

Supplemental Benefits

While supplemental benefits can significantly enhance enrollee health and wellness, there is a lack of transparency regarding their utilization and effectiveness. We appreciate CMS' recent requirement that MA plans report encounter data for all supplemental benefits, including vision, hearing, fitness, and dental services. However, encounter data have multiple flaws, including completeness and accuracy. CMS should consider alternatives to using encounter data for this purpose, such as independent evaluations, enhanced performance metrics, and beneficiary feedback mechanisms.

Standardization of supplemental benefits is also a significant challenge that creates challenges for CMS in evaluating supplemental benefits across MA plans and for beneficiaries in comparing MA plans. The Medicare Payment Advisory Commission (MedPAC) has called for standardization of supplemental benefits to streamline comparisons and choice for beneficiaries. For example, in their June 2023 *Report to the Congress*, MedPAC recommended standardizing benefits to address disparities in outcomes among beneficiaries and to align more closely with fee-for-service payment rates. *CMS should work with Congress to expand its authority to carry out standardization of supplemental benefits*.

In recent rulemaking, CMS finalized that plans must provide a mid-year notification to enrollees about unused supplemental benefits, including details about each benefit's scope, cost-sharing, and access instructions. The goal is to ensure that beneficiaries are aware of and can access the benefits they are entitled to, but we contend this is not sufficient. The Alliance urges CMS to increase the frequency of these notices, and specifically, on a quarterly basis and as part of every explanation of Medicare benefits delivered to plan enrollees. Ideally, MA plans would have this information available in real-time on their website, accessible by enrollees upon log-in to their accounts.

Marketing

Misleading marketing practices by MA plans continue to be reported by enrollees, particularly regarding access to their physicians and the coverage of medications. This has been a significant challenge for patients with chronic diseases under the management of a specialty physician, namely those that rely on highly complex medications, such as biologics that are now used in a wide range of conditions.

Despite newly revised regulations that address how MA plans are marketed, CMS did not make any specific requirements to address the impact on access to physicians and medications when beneficiaries move from traditional Medicare to MA, or between MA plans. The newly finalized requirements for the pre-enrollment checklist (PECL), specifically the addition of "effect on current coverage," is too vague to ensure these details are addressed, despite CMS acknowledging that beneficiaries have been misled by

agents on these very topics. CMS must explicitly require plans to inform prospective enrollees whether their doctor(s) will be in the plan network, and if a referral is required, during the plan year for which they are enrolling, as well as whether their medication(s) are on the plan's formulary, if the medication(s) are subject to cost-sharing based on tiering, and if there are any associated utilization management requirements to access their medication(s).

While it seems logical that this information would be shared as part of the PECL, some Alliance organizations have reported that this has not been the experience of their MA-enrolled patients. We urge CMS to require MA plans to discuss how access to specialists and therapies will be impacted as part of the "effect on current coverage" component of the PECL.

Quality Measures

The Alliance has long recommended additions to the quality measures on which MA plans are measured, which we reiterate herein.

First, we appreciate CMS' efforts to address challenges that practices and patients face with prior authorizations, particularly those policies finalized in recent rulemakings. As a complement to these efforts, we support a new quality measure — Level I Denials Upheld Rate Measure — recently recommend by the Partnership for Quality Measurement (PQM) Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Group for adoption in the Star Ratings program. The Alliance agrees with the group's rationale that the measure "could reduce frustration of obtaining unnecessary prior authorizations with Medicare Advantage" and urges CMS to adopt this measure through rulemaking for CY 2026 and beyond.

Second, CMS previously solicited and received feedback on conducting a survey of physicians about their interactions with plans on behalf of beneficiaries, but said "the vast majority of commenters recommended against a mandatory survey," citing concerns such as burden, potential for skewed results, and that most plan interactions are with centralized staff. Despite CMS' rejection of such a survey, the Alliance continues to strongly support a Star Ratings measure based on a survey of physicians' experiences (which would include the physician's clinical and administrative staff) with Medicare Advantage plans, and asks the agency to adopt this measure for CY 2026 and beyond.

Questions that should be included as part of this survey-based measure should focus on the following:

- Network adequacy, including the accuracy of physician directories and physician termination and reinstatement practices;
- Payment and reimbursement practices, including the sufficiency of payment rates, the volume of denials and post-payment medical reviews, and other tactics that deny or delay payment after services are rendered;
- Contracting, including the process used to negotiate plans' payments to physicians;
- Utilization management, including prior authorization practices, step-therapy requirements, non-medical switching of medications, and other administrative barriers that inappropriately diminish or slow beneficiary access to medically necessary diagnostic and therapeutic services and treatment; and,
- Other administrative burdens, including referral requirements and the number and type of
 medical record documentation requests, including those required as part of CMS' Risk
 Adjustment Data Validation and those required by the plan to establish additional diagnoses for
 purposes of increasing beneficiary risk scores.

We urge CMS to propose this potential new measure concept in the CY 2026 rulemaking cycle, and to ensure the physician community is made aware of the proposal and the opportunity to comment through the usual channels that reach this constituency.

Other Data Needs: Medications

As CMS has implemented provisions of the *Inflation Reduction Act* (IRA), specifically those related to drug price negotiation, some Alliance organizations have reiterated their concern about the practice and impact of "white bagging." MA plans have increasingly turned to white bagging, which essentially shifts coverage for medical benefit drugs (i.e., those administered by a physician, or "Part B" drugs) to the pharmacy benefit (i.e., self-administered drugs, or "Part D" drugs), which allows the plans to access manufacturer rebates and pass on more costs to patients.

Specialty pharmacy-filled drugs that are provider-administered should be kept separate from traditional self-administered medications. Below are two methods by which this could be achieved:

- Merging the prescription drug event (PDE) data with Part B claims data. CMS could possibly
 identify cases of white bagging if the agency merged PDE data with provider-submitted claims
 for drug administration services. CMS is already using PDE data combined with Part B claims
 data to implement the low-spend Medicare drug exclusion.
- Revise the PDE collection tool to capture "white bagging." CMS could capture whether the medication was sent to a provider's office, or identify NDC codes that are for medications that are provider-administered, enabling a better understanding of the prevalence of white bagging.

If CMS does not collect and act on data related to white-bagged drugs, we are concerned that MA plans, including their pharmacy benefit managers (PBMs) and specialty pharmacies, will inappropriately access maximum fair prices, potentially leading to an increased prevalence of white bagging. We urge CMS to adopt the above recommendations to address white bagging.

We appreciate the opportunity to comment on these important issues and welcome the opportunity to meet with you to discuss them in more detail. Should you have any questions or wish to schedule a meeting, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association

¹ The Coalition of State Rheumatology Organizations (CSRO) describes white bagging as a medication acquisition process whereby insurers require physicians to accept and administer a medication from a specialty pharmacy rather than the manufacturer or wholesaler. In addition to safety concerns, white bagging shifts medications from the medical benefit to the pharmacy benefit. https://csro.info/advocacy/our-issues/specialty-pharmacy-mandates-white-bagging

American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
The Society of Interventional Radiology