



August 31, 2022

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

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

Dear Administrator Brooks-LaSure:

The Cystic Fibrosis Foundation is a national organization dedicated to curing cystic fibrosis (CF). We invest in research and development of new CF therapies, advocate for access to care for people with CF, and fund and accredit a network of specialized CF care centers.

Cystic fibrosis is a life-threatening genetic disease that affects nearly 40,000 children and adults in the United States. Through careful, aggressive, and continuously improving disease management, the average life expectancy for people with cystic fibrosis has risen steadily over the last few decades. In addition to advances in care, recently approved genetically-targeted drugs that address the underlying cause of CF are available for patients with specific genetic profiles and have contributed to the increases in life expectancy. With recent advancements in treatment options, more people with CF are aging onto Medicare than ever before. This development highlights the extraordinary advancements in care; however, the current Medicare delivery model, current coverage policies, and cost of care continues to be a barrier to accessing needed treatments and prescription drugs for people with CF.

We provide the following recommendations to the Centers for Medicare and Medicaid Services (CMS) in response to the Request for Information on Medicare.

Objective 1: Advancing Health Equity

1. *What steps should CMS take to better ensure that all Medicare Advantage (MA) enrollees receive the care they need, including but not limited to the following:*
 - *Enrollees from racial and ethnic minority groups.*
 - *Enrollees who identify as lesbian, gay, bisexual, or another sexual orientation.*
 - *Enrollees who identify as transgender, nonbinary, or another gender identity.*
 - *Enrollees with disabilities, frailty, other serious health conditions, or who are nearing end of life.*
 - *Enrollees with diverse cultural or religious beliefs and practices.*
 - *Enrollees of disadvantaged socioeconomic status.*
 - *Enrollees with limited English proficiency or other communication needs.*

While CMS is charged with overseeing and administering the Medicare program, we understand there are limited data reporting mechanisms available to provide CMS with information about plan-level coverage denials, appeals, and delays in care resulting from plan administrative processes. These data are crucial for identifying disparities and where policy interventions are needed to address inequities and ensure meaningful oversight of MA plans. CMS should establish standardized reporting metrics and that data should be made publicly available and be stratified by insurer.

Furthermore, comprehensive, transparent and timely data on key indicators of enrollment is critical for CMS, plans, and other stakeholders to monitor enrollment and identity concerns. There are clear gaps in available information on quality and access as well as specific cost and utilization data across all MA marketplace. We ask CMS to require transparency throughout the program as an essential step in gathering and strengthening data necessary to accurately assess the MA program and promote alignment within and across Medicare.

- 3. What are effective approaches in MA for screening, documenting, and furnishing health care informed by social determinants of health (SDOH)? Where are there gaps in health outcomes, quality, or access to providers and health care services due partially or fully to SDOH, and how might they be addressed? How could CMS, within the scope of applicable law, drive innovation and accountability to enable health care that is informed by SDOH?*

Given the increasing recognition about the importance of social determinants of health, CMS should explore ways to require all MA plans to screen for social risk factors, make referrals for support services, and track the outcomes of those referrals. It is important for plans to monitor enrollee use of referred services in order to better understand and address the barriers to access. This data will also help ensure that the referrals placed are for sustainable interventions.

- 5. What socioeconomic data do MA plans leverage to better understand their enrollees and to inform care delivery? What are the sources of this data? What challenges exist in obtaining, leveraging, or sharing such data?*

MA plans can leverage zip code level data and neighborhood level socioeconomic disadvantage data, measured by the area deprivation index (ADI). These measurements can help clinicians to better predict and understand patient needs, thus better informing care. In CF research, ADI has been used to better understand the health of pediatric people with CF and their health outcomes.¹ The ADI has been used by clinicians in many settings, including those with COPD, which found a positive correlation between more disadvantaged neighborhoods and worse COPD outcomes.² This study suggests that contextual factors from the ADI could be used to inform intervention strategies.

- 7. What food- or nutrition-related supplemental benefits do MA plans provide today? How and at what rate do enrollees use these benefits, for example, for food insecurity and managing chronic conditions? How do these benefits improve enrollees' health? How are MA Special Needs Plans (SNPs) targeting enrollees who are in most need of these benefits? What food- or nutrition-related policy changes within the scope of applicable law could lead to improved health for MA enrollees? Please include information on clinical benefits, like nutrition counseling and medically-*

¹ <https://pubmed.ncbi.nlm.nih.gov/33258546/>

² <https://pubmed.ncbi.nlm.nih.gov/32440110/>

tailored meals, and benefits informed by social needs, such as produce prescriptions and subsidized/free food boxes.

Food insecurity is prevalent in the CF community with one in three people with CF reporting experiencing food insecurity: three times the national average.³ The CF Foundation has evaluated intervention options to increase access to affordable food for the community, including exploring supplemental benefits – such as coverage of medically tailored meals – offered by health plans. In recent efforts, the CF Foundation facilitated a collaboration between CF clinicians and a local community organization providing medically tailored meals. This pilot intervention has been positively received by the CF community, with users reporting increased access to food, improved diet quality, increased energy, and savings of time and money.

Non-CF-specific research on medically tailored meals has found numerous benefits for both the recipients of medically tailored meals and their insurers, including fewer inpatient admissions, lower healthcare costs, improved diet quality, and lower rates of food insecurity.^{4 5} One study that evaluated benefits for individuals dually eligible for Medicare and Medicaid found that individuals receiving medically tailored meals had 50% fewer inpatient admissions and 70% fewer emergency department visits than similar patients not enrolled in the meal program. Researchers found an average net savings of \$220 per patient per month (16% savings on total medical expenditures) after factoring in the costs of the medically tailored meals.⁶

While some of the existing medically tailored meal programs rely on private donations, many also rely on health plans and systems partnering to provide meal interventions to their members. CMS should evaluate the effectiveness of these programs across chronic disease types and provide coverage options through MA SNPs.

Objective B: Expand Access: Coverage and Care

1. *What tools do beneficiaries generally, and beneficiaries within one or more underserved communities specifically, need to effectively choose between the different options for obtaining Medicare coverage, and among different choices for MA plans? How can CMS ensure access to such tools?*

Choosing among plans can be difficult even for individuals who are well versed in Medicare plan type and enrollment. The CF Foundation has a team of Alliance of Information and Referral Systems (AIRS) accredited case managers who help with complex challenges, including and understanding insurance, troubleshooting insurance coverage issues, and provide side-by-side comparison of available plans for people with CF or their loved ones. Even with a wide breadth of knowledge and expertise, our case managers have a hard time accessing basic information across Medicare, Medigap, and Medicare Advantage plans.

The enrollment process, details regarding available benefits, cost-sharing arrangements and premium costs, and network directories should be readily available to all Medicare beneficiaries and presented in

³ https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/59/

⁴ <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2730768>

⁵ <https://pubmed.ncbi.nlm.nih.gov/30421335/>

⁶ <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2017.0999>

a clear and understandable manner. For example, Medicare Part D previously had a side-by-side comparison tool that could be downloaded as a PDF and that allowed consumers to review drugs covered in each plan in a comprehensible manner. Recently that formatting was removed from the website making it more difficult for enrollees to compare coverage options. Additionally, comparing MA plan networks and available benefits still remains a challenge for beneficiaries due to the lack of readily available plan information. Beneficiaries need to be fully aware of any differences in coverage that could result in delays to appropriate care, such as prescription drug coverage and any potential prior authorizations that were unnecessary on their previous plan. MA Plans can also make significant changes to benefit options, cost-sharing arrangements, networks, and other details from year to year, making comparison even more difficult. The CF Foundation asks for these tools to be updated to be more consumer friendly and ensure beneficiaries are enrolling in appropriate plans that meet their needs.

- 5. What role does telehealth play in providing access to care in MA? How could CMS advance equitable access to telehealth in MA? What policies within CMS' statutory or administrative authority could address access issues related to limited broadband access? How do MA plans evaluate the quality of a given clinician or entity's telehealth services?*

We support CMS's goal to research the expanded use and availability of telehealth as well as the continuous efforts to collect data on the uses and outcomes of telehealth, including data to measure access and outcomes across different demographic groups. Starting in 2020, MA plans were allowed to include telehealth benefits as part of the basic Medicare Part A and B benefits package due to the temporary expansion through the public health emergency. We recommend CMS to maintain some of these flexibilities as part of MA plans permanently.

We urge CMS to evaluate and expand the types of clinicians who can provide online assessment and management under Medicare. People with CF rely on a multidisciplinary, specialized care team to ensure best possible outcomes and patients would benefit from the option of having virtual check-ins with all members of the care team. The CF clinical care team includes physicians, nurses, dietitians, social workers, and respiratory therapists – each of whom plays a unique role in managing CF care. For example, individuals with CF require a specialized diet and nutritional plan that is high in calories, proteins, vitamins, and minerals. CF dietitians are trained to assess daily food intake and overall nutritional status, which helps the individual with CF work towards optimal body weight and the calories and nutrients needed to fight off lung infections and maintain lung function. Brief virtual check-ins with dietitians would allow patients to address issues with feeding tubes, formula concentrations, diet, or vitamins and supplements in between their regularly quarterly visits with the full care team. Such access to all members of the care team could help patients better maintain and manage their care, leading to more consistent and better outcomes.

Furthermore, the Foundation commends CMS for establishing the benefit of audio-only telephone evaluation and management services during the time of the COVID-19 public health emergency. CMS has helped ensure patients without access to the internet or video platform – through a computer or smartphone – are still able to receive needed care. This flexibility is particularly important for rural and low-income populations who are more likely to have limited or no access to the internet. For patients who do not have sufficient broadband to support video conferencing or do not have any internet access at all, telephonic visits with their care team are their only option for access remote care. Providers and patients also encounter technical issues with the platform or broadband, and some patients do not have the technological expertise to navigate video platforms—all of which can lead to the need for audio-only

visits. Anecdotally, one CF physician in Indiana estimates that 25 to 30 percent of her telehealth appointments are conducted over the phone either because of broadband or other technological issues.

While audio-only visits are not suitable for all health care services and are not a substitute for in-person care, there are a number of aspects of a regular CF visit that can be conducted through the phone. For instance, clinicians can review medical history, current medications, and symptoms, and adjust a patient's care plan. CF patients and care teams can also review data from home spirometers to track trends in lung function. For CF providers, listening to a patient's cough can also provide actionable information about potential exacerbations. The use of telehealth should be determined by the preferences of the patient and clinical judgement of the provider, and we urge CMS to make audio-only visits a permanent benefit.

- 6. What factors do MA plans consider when determining whether to make changes to their networks? How could current network adequacy requirements be updated to further support enrollee access to primary care, behavioral health services, and a wide range of specialty services? Are there access requirements from other federal health insurance options, such as Medicaid or the Affordable Care Act Marketplaces, with which MA could better align?*

For individuals with complex, chronic conditions like CF, which require a provider care team of specialists, it is vital to ensure that plans' provider networks are of sufficient size and composition, and that provider directories are accurate, informative, and clear. This is particularly important for patients from underserved communities, who have experienced discrimination in health care settings and systematically worse health outcomes. As CMS evaluates network parameters for MA plans, we suggest networks should be evaluated on their ability to provide culturally- and linguistically competent care as well as care accessible to people with disabilities. This means, among other things, a rigorous assessment of whether a network includes sufficient providers and/or provides sufficient access to appropriate language services to ensure limited English proficiency individuals can obtain timely care in their preferred language, as well as assessment of physical, language, and other accessibility. Further, networks must ensure access to culturally appropriate care reflecting the diversity of enrollees' backgrounds and attuned to traditionally underserved communities, including people of color, immigrants, people with disabilities, and LGBTQ individuals. To enable consumers to identify the plans and providers likely to meet their needs, all health plans must be required to indicate in their provider directories the languages of other than English spoken by any provider and/or their staff.

CMS should look to the Affordable Care Act Marketplaces to align with providing current online provider directories. Federal law requires that marketplace health plans maintain an adequate network of providers, and to maintain and up-to-date online provider directories. These protections are designed to ensure that marketplace enrollees have timely, meaningful access to the care and services they need, as well as accurate information sufficient to enable them to understand plans' networks and identify the plans and providers most likely to meet their needs. Consumers looking to enroll in MA plans would benefit from having similar accurate information readily available.

Finally, we urge CMS to work with Congress to address access to care across state lines through provider licensure reciprocity and MA plan network coverage. For those who rely on out-of-state care centers to help manage their CF, clinician licensure reciprocity is an important tool to make remote care accessible. While many states have adjusted their licensure requirements during the public health emergency to enable greater flexibility of care and telehealth access for patients who live in a different state from their providers, the variability from state-to-state results in some individuals with CF still struggling to

maintain continuous care with their established care team. We recognize the MA plan structure and network operates on a state basis, the CF care model does not. CMS should work to strengthen access to providers across state borders, ensuring patients have coverage for their established care team either through telehealth or in-person visits.

8. *How are enrollees made aware of supplemental benefits for which they qualify? How do enrollees access supplemental benefits, what barriers may exist for full use of those benefits, and how could access be improved?*

As mentioned above, many enrollees are not aware of supplemental benefits and often find reviewing plans to be confusing due to lack of cost break down and explicit benefit list. We ask CMS to require plans to provide transparent information about supplemental benefits, including but not limited to, cost requirements and limitations on coverage.

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?*

Nearly all Medicare Advantage enrollees are in plans that require prior authorization for some services.⁷ This includes part B drugs and inpatient hospital stays. This is in contrast to traditional Medicare, which does not use prior authorization or other utilization management techniques to nearly the same extent as MA plans.

Prior authorization is a time-consuming process that burdens providers, diverts valuable resources away from direct patient care, and causes delays in patient access to needed treatment.⁸ This process is particularly burdensome on the CF community as people with CF must adhere to intensive, ongoing treatment plans in order to stay healthy. Prior authorization policies present a unique set of challenges for people with CF and other lifelong, chronic diseases. For CF patients, their diagnosis will never change; they will always need these drugs and it is unnecessary to require these providers to continuously request reauthorizations and provide duplicative information in order to demonstrate the medical necessity of these therapies.

All Medicare beneficiaries should have equal access to medically necessary care and consumer protections, and those enrolled in MA plans should not be subjected to more restrictive rules and requirements.

Objective C: Drive Innovation to Promote Person-Centered Care

8. *How do beneficiaries use the MA Star Ratings? Do the MA Star Ratings quality measures accurately reflect quality of care that enrollees receive? If not, how could CMS improve the MA Star Ratings measure set to accurately reflect care and outcomes?*

⁷ <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-premiums-out-of-pocket-limits-cost-sharing-supplemental-benefits-prior-authorization-and-star-ratings/>

⁸ <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf>

There are many ways in which MA Star Rating may be improved. Although the MA Star Rating program is promoted as a tool for consumer comparison of plans, it does not adequately do so and the system is too simplistic for differentiating plans in a way that benefits enrollees. While the star ratings help enrollees screen out the lowest-performing plans, they do not help enrollees understand how well plans serve people like themselves. As mentioned above, people with CF have a unique treatment regimen, and having insights to how certain plans worked for enrollees with a similar complex, chronic conditions, such as specific medication and provider coverage, would greatly improve the quality of the star rating.

- 9. What payment or service delivery models could CMMI test to further support MA benefit design and care delivery innovations to achieve higher quality, equitable, and more person-centered care? Are there specific innovations CMMI should consider testing to address the medical and non-medical needs of enrollees with serious illness through the full spectrum of the care continuum?*

We recommend the Center for Medicare and Medicaid Innovation (CMMI) explore policies that are a clinically based alternative to prior authorization, such as “gold carding,” to streamline the administrative process, ensure timely access to medications and reduce delays in care. “Gold carding” or other alternative approaches to utilization management, allow providers to meet certain criteria and then receive an exemption that waives prior authorization requirements. As mentioned above, CF is a progressive, life-long disease, and interruptions in care puts patients at risk of irreversible lung damage and costly hospitalizations. Prior authorization policies can create delays in care and often require people with CF to continuously document their need for drugs that they may take for their entire life and are prescribed by clinicians who specialize in this disease. We ask CMMI to explore a demonstration removing these burdensome policies.

The CF Foundation appreciates the opportunity to provide comment on the Medicare Request for Information. We look forward to working with CMS on these critical issues to ensure access and affordability for people with CF.

Sincerely,



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Senior Vice President, Policy & Advocacy
Cystic Fibrosis Foundation