



March 4, 2022

Meena Seshamani, M.D., Ph.D.
Director, Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (CMS-2022-0021)

Dear Dr. Seshamani:

On behalf of people living with cystic fibrosis, we write to provide public comment on the Centers for Medicare and Medicaid Services' (CMS) 2023 Advance Notice of Methodological Changes for Medicare Advantage Capitation Rates and Part C and Part D Payment Policies.

About Cystic Fibrosis & the Cystic Fibrosis Foundation

Cystic fibrosis (CF) is a severe, progressive genetic disease that affects over 30,000 children and adults in the United States. CF causes the body to produce thick mucus that clogs the lungs and other organ systems, which results in lung damage, life-threatening infections, and other complications. As a complex, multi-system condition, CF requires targeted, specialized treatment regimens. Cystic Fibrosis is a costly, complex, disease and surveys of patients and families have found that people with CF are at risk of experiencing significant cost burden across all income brackets.¹ Further, research exists that shows the unique burden of social risk factors – such as food insecurity – within the CF community.^{2,3} Despite significant advances in CF care, CF remains a life-shortening disease.

As the world leader in the search for a cure for CF, the Cystic Fibrosis Foundation's mission is to give all people with CF the opportunity to lead long, fulfilling lives. We do so by funding research and drug development, advancing high-quality, specialized care, and partnering with the CF community to ensure that people with cystic fibrosis and their families have the tools, resources, and support they need to thrive.

We welcome the opportunity to review and share our thoughts on this Advanced Notice and are encouraged to see that it addresses several high priority topics for the CF community, including advancing health equity and minimizing the negative impacts of social risk factors. Throughout our comments you will see recommendations to look at not just socioeconomic status, but also other social risk factors. We encourage CMS to evaluate, whenever feasible, opportunities to incorporate a variety of social risk factors into their models and reporting measures.

¹ Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Cost, coverage, and the underuse of medications among people with CF" (2020). *Health Policy and Management Issue Briefs*. Paper 57. https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/57

² Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Risk indicators of food insecurity in the CF population" (2021). *Health Policy and Management Issue Briefs*. Paper 59. https://hsrc.himmelfarb.gwu.edu/sphhs_policy_briefs/59

³ Lim, JT, Ly, NP, Willen, SM, et al. Food Insecurity and Mental Health During the COVID-19 Pandemic in Cystic Fibrosis Households. *Pediatric Pulmonology*. 2022; 1- 7. doi:10.1002/ppul.25850

CMS-HCC Risk Adjustment Model for CY 2023

We are pleased to see throughout the Advanced Notice that there are efforts to understand and address the impacts of social risk factors on beneficiaries. We support the proposal of including zip code data to better capture regional risk variation. Within the CF population, we have found that additional socioeconomic data – such as education level, employment status, and household income – have adverse effects on health outcomes and CMS should consider inclusion of those data as well in its effort to more accurately quantify beneficiary risk.^{4,9,9,5}

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Potential New Measure Concepts and Methodological Enhancements for Future Years

Driving Health Equity (Part C and D)

The CF Foundation applauds the efforts of CMS to promote health equity and remove incentives for plans to avoid caring for disadvantaged populations. Incorporating social risk factors into the stratification and rating measures acknowledges that health outcomes are impacted by factors beyond the medical care a person receives. However, the CF Foundation would like to highlight that we disagree with CMS's use of "reduced compliance to medical regimens" as an example of a social risk factor. Research has found that people with CF who struggle with challenges such as food insecurity or out-of-pocket costs are more likely to make tradeoffs that forego their standard care regimen and a lack of adherence to a care regimen is often the result of a variety of different social factors.⁶

Stratified Reporting (Part C and D)

We are encouraged by the changes in Part C and D to further equitable reporting of plan performance for different populations and we support efforts to stratify all applicable measures by socioeconomic status. For the CF community, low socioeconomic status is associated with more rapid lung function decline, increased exacerbation rates, increased health care utilization, and decreased survival in people with CF.⁷ We also encourage CMS to consider a broad range of social risk factors in their stratification of measures; for instance, research in the CF population has found that nongenetic factors – such as physical environment – are associated with adverse pulmonary outcomes, growth, immune function, and nutritional outcomes in children with CF.^{8,9,10}

It is essential that stratified reporting data is made publicly available to ensure that people with CF have the ability to make informed decisions when selecting their insurance plan. In 2021, over 150 people from the CF community called the CF Foundation's 1:1 case management program for assistance in evaluating Medicare plan options, showcasing the importance of having standardized information to ease the decision-making process for people with CF and their families.

⁴ Gabriela R. Oates & Michael S. Schechter (2016) Socioeconomic status and health outcomes: cystic fibrosis as a model, *Expert Review of Respiratory Medicine*, 10:9, 967-977, DOI: 10.1080/17476348.2016.1196140

⁵ Gerald T. O'Connor, Hebe B. Quinton, Terry Kneeland, Richard Kahn, Thomas Lever, Joanne Maddock, Priscilla Robichaud, Mark Detzer, Donald R. Swartz; Median Household Income and Mortality Rate in Cystic Fibrosis. *Pediatrics* April 2003; 111 (4): e333–e339. 10.1542/peds.111.4.e333

⁶ Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Cost, coverage, and the underuse of medications among people with CF" (2020). *Health Policy and Management Issue Briefs*. Paper 57. https://hsr.c.himmelfarb.gwu.edu/sphs_policy_briefs/57

⁷ Albon D, Bruschiwein H, Soper M, et al. Impact of COVID-19 on social determinants of health for adults with cystic fibrosis. *Therapeutic Advances in Respiratory Disease*. January 2021. doi:10.1177/17534666211037459

⁸ Kopp BT, Ortega-García JA, Sadreameli SC, et al. The Impact of Secondhand Smoke Exposure on Children with Cystic Fibrosis: A Review. *International Journal of Environmental Research and Public Health*. 2016 Oct;13(10). DOI: 10.3390/ijerph13101003. PMID: 27754353; PMCID: PMC5086742.

⁹ Ong T, Schechter M, Yang J, et al. Socioeconomic Status, Smoke Exposure, and Health Outcomes in Young Children with Cystic Fibrosis. *Pediatrics*. 2017 Feb;139(2). DOI: 10.1542/peds.2016-2730. PMID: 28093464; PMCID: PMC5260155.

¹⁰ Oates GR, Baker E, Rowe SM, et al. Tobacco smoke exposure and socioeconomic factors are independent predictors of pulmonary decline in pediatric cystic fibrosis. *Journal of Cystic Fibrosis: Official Journal of the European Cystic Fibrosis Society*. 2020 Sep;19(5):783-790. DOI: 10.1016/j.jcf.2020.02.004. PMID: 32081643; PMCID: PMC7429279.

Health Equity Index (Part C and D)

We support the consideration of incorporating an Area Deprivation Index into the Health Equity Index. For people living with CF, respiratory outcomes are associated with area deprivation level. A study found that those residing in the worst tertile for area deprivation have lower respiratory outcomes, including lower lung function, more intravenous treatment nights, and higher odds of pulmonary exacerbations.¹¹

Measure of Contracts' Assessment of Beneficiary Needs (Part C)

The CF Foundation appreciates and agrees with the efforts made to increase and standardize social risk factor screening for beneficiaries. Within the CF population, social risk factors can be pervasive across all levels of income due to the high cost of CF care.¹² We support the notion that everyone, regardless of perceived risk status, should be screened for these factors. The CF Foundation is similarly working to support the CF clinician community in standardizing their screening approach. While we recognize that CMS does not require a specific social needs assessment tool be used by Medicare Advantage plans, we encourage CMS to provide or recommend a validated tool for plan use. This would allow for more consistent recommendations on how screenings should be administered and more consistency in understanding the needs of the plan population.

Screening and Referral to Services for Social Needs (Part C)

We also support the proposed measure to screen and make referrals based on social needs and to publicly display this as a Star measure. We applaud the efforts to ensure that this new measure does not just include screening, but also referrals for those who screen positive. However, this measure does not provide sufficient information about whether the beneficiary accesses the referred intervention. Plans should also monitor beneficiary 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. We urge CMS to clarify how referrals will be evaluated or to expand this measure to include a follow up screening to see if the beneficiary's social needs have been met.

The Cystic Fibrosis Foundation appreciates the opportunity to provide input on this important advanced notice. We stand by to answer any questions you may have. Please contact Olivia Dieni, MPH, at odieni@cff.org or 240-200-3715 to discuss further.

Sincerely,



Mary B. Dwight
Chief Policy & Advocacy Officer
Senior Vice President of Policy and Advocacy

¹¹ Oates G, Rutland S, Juarez L, Friedman A, Schechter MS. The association of area deprivation and state child health with respiratory outcomes of pediatric patients with cystic fibrosis in the United States. *Pediatr Pulmonol*. 2021 May;56(5):883-890. doi: 10.1002/ppul.25192. Epub 2020 Dec 14. PMID: 33258546; PMCID: PMC8035176.

¹² Seyoum, Semret; Regenstein, Marsha; and Nolan, Lea, "Risk indicators of food insecurity in the CF population" (2021). *Health Policy and Management Issue Briefs*. Paper 59. https://hsrcc.himmelfarb.gwu.edu/sphhs_policy_briefs/59