Diabetes Advocacy Alliance™

September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1751-P
P.O. Box 8016,
Baltimore, MD 21244-8016

Re: **File Code CMS–1770–P**. Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Dear Administrator Brooks-LaSure:

On behalf of the 29 member organizations of the Diabetes Advocacy Alliance (DAA), we are pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) regarding the CY 2023 Medicare Payment Policies under the Medicare Physician Fee Schedule (PFS) proposed rule (file code CMS-1770-P).

The DAA is diverse in scope, with our members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic.

DAA members share a common goal of elevating diabetes on the national agenda so we may ultimately defeat this treatable, but also potentially deadly chronic disease. We are committed to advancing person-centered policies, practical models, and legislation that can improve the health and well-being of people with diabetes and prediabetes. An essential component to our goal is combatting health disparities and addressing social determinants of health. Our advocacy to policymakers highlights key strategies to prevent, detect and manage diabetes and care for those affected by it. Our educational outreach also illustrates the health equity implications of existing or new policies, regulations, and legislation, and provides alternatives to address the drivers of these inequities.

Introduction

DAA members appreciate that CMS made changes in the 20222 Medicare PFS that have improved the ability of Medicare Diabetes Prevention Program (MDPP) providers to offer the program to beneficiaries with prediabetes:

- Elimination of Year 2 of the MDPP, which has made the program attractive to more MDPP eligible organizations and beneficiaries.
- Redistribution of a portion of the ongoing maintenance sessions phase performance payments to certain core and core maintenance session performance payments to help cover reasonable costs of MDPP suppliers to deliver the MDPP set of services.
- Elimination of the Medicare enrollment application fee ($599) for potential MDPP suppliers.

However, DAA members are frustrated and concerned that there is nothing in the CY 2023 Medicare PFS that addresses the many changes still needed to adequately meet the needs of beneficiaries with prediabetes and diabetes, especially those beneficiaries who face health inequities. The rate of type two diabetes is increasing - not decreasing - across all populations but especially among Black and Latino/a Americans.[1] The DAA has pointed out needed changes many times in the past few years in letters and meetings with CMS officials, and we will continue to advocate for these needed improvements, both with CMS and members of Congress.

DAA Comments: Focused on Pages 45941-45944, Section 38, RFI for Medicare Potentially Underutilized Services

The DAA has focused its comments this year on Section 38, Request for Information (RFI) for Medicare Potentially Underutilized Services. **The DAA notes that four Medicare benefits for people with prediabetes and diabetes are severely underutilized: the Medicare Diabetes Prevention Program (MDPP); Diabetes Self-Management Training (DSMT); Medical Nutrition Therapy (MNT); and Intensive Therapy (IBT).** The DAA appreciates that CMS has expressed interest in addressing health inequities by reducing barriers to these services, whether policies and actions are targeted to the beneficiary, the provider, or increase general awareness of the prediabetes issue.

As CMS is aware, inequities abound in the American health care system and Medicare is no exception. The DAA believes that by taking the specific actions that we list below, Medicare can improve access for beneficiaries by reducing barriers to the availability of MDPP, DSMT, MNT, and IBT services.

Actions that CMS Could Take Now and Specify in the CY 2023 Medicare PFS

CMS could take the following actions to reduce health inequities in the use of the four services mentioned above. For the MDPP and DSMT, these actions are supported by evidence-based recommendations issued by the National Clinical Care Commission (NCCC) in its report to Congress, January 2022. The NCCC did not directly address MNT and IBT, but the DAA supports actions to improve access and reduce inequities in receipt of MNT and IBT services.

Medicare Diabetes Prevention Program (MDPP)

1. CMS should act upon the NCCC recommendation to provide coverage for the A1c test without a deductible when used to screen for prediabetes.[2] CMS lists "screening for diabetes" as a service that is

[1] The Centers for Disease Control and Prevention (CDC) routinely publicizes this statistic.
[2] See NCCC report Recommendation 5.2 on p. 63.

high value and potentially underutilized in its list of underutilized services in the RFI within the CY 2023 Medicare PFS. In addition to NCCC support for this recommendation, the American Medical Association also supports coverage for the A1c test when used to screen for prediabetes as documented in their quality measure, "Screening for Abnormal Glucose."

2. In a study reported in 2019 in the *Journal of the American Board of Family Medicine*, which examined 107,000 US office visits between 2012-2015, the data showed that physicians are equally likely to screen for diabetes with the A1c test as the fasting plasma glucose test. The study authors suggest lack of coverage for the A1c test in Medicare populations is likely leading to inequities and missed opportunities for Medicare beneficiaries with prediabetes to be identified and referred to Medicare Diabetes Prevention Programs. Medicare beneficiaries whose physicians use the A1c test to screen for prediabetes and diabetes must pay out of pocket for this test to determine if they qualify for a diabetes prevention program:
    - **"This study also shows a slight preference for A1C (33.8%) over fasting glucose (31.6%), as more visits involved the use of A1C; however, there is no significant difference. This may also account for why patients with private insurance were more likely to be screened compared to patients with Medicare, Medicaid, other, or uninsured."**

The DAA urges CMS to cover the A1c test to screen for prediabetes and diabetes.

3. The NCCC has recommended that Congress promote coverage for all proven-effective modes of delivery (for example, in-person, online, and distance learning [telehealth]) for evidence-based interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards.[3]
    - For fully virtual diabetes prevention programs, DAA members believe that CMS has the authority under section 3021 of the Affordable Care Act (and as established by section 1115A of the Social Security Act) to expand the model test such that fully virtual programs that have met the CDCs National DPP standards can apply to become Medicare Diabetes Prevention Program (MDPP) providers. But since CMS has not acted, DAA members continue to support passage of the **PREVENT DIABETES Act** (H.R. 2807, S. 2173), which would require CMS to modify the MDPP Expanded Model to allow fully virtual program that have met National DPP standards to apply.

The DAA urges CMS to act upon the NCCC recommendation that the MDPP be approved as a permanent covered benefit – not only a model expansion service – and as noted above, coverage of MDPP should be expanded to include ALL CDC fully recognized National Diabetes Prevention Program providers, regardless of the delivery modality of care. Furthermore, the "once in a lifetime" limit on participation in the MDPP should be removed.[4]

4. The DAA urges CMS to act upon the NCCC recommendation to reduce or eliminate differences in program eligibility, delivery modalities, and duration between the National DPP and the MDPP.[5]

5. The DAA urges CMS to act upon the NCCC recommendation for funding to support the testing of new payment models that allow for greater upfront payments and more equitable risk-sharing between CMS and MDPP program delivery organizations. In addition, there should be an increase in payment levels to MDPP program delivery organizations to make MDPP programs financially sustainable.[6]

[3] See NCCC report Recommendation 5.6 on p. 66.
[4] See NCCC report Recommendation 5.7 on p. 67.
[5] See NCCC report recommendation 5.8 on p. 68.
[6] See NCCC report Recommendation 5.9 on p. 69.

6. Also, DAA members remain very concerned about CMS requirements regarding submission of social security numbers and other personally identifiable information by volunteer board members of community-based nonprofit organizations, such as the YMCA of the USA, a DAA member, that apply for participation in the MDPP. CMS acknowledges that the MDPP benefit is underutilized, yet has not addressed the concerns expressed by potential MDPP suppliers that are non-clinical, community-based nonprofit organizations, and which are stymied by this ongoing requirement, as expressed in the CY 2023 Medicare PFS proposed rule:

    - "We have received questions over the years from non-profit corporations regarding the need to disclose information on the application about volunteer or ceremonial board members. We have long required such persons to be reported for two reasons. First, we believe section 1124(a) of the Act is clear that all directors must be listed. Again, it does not distinguish between for-profit and non-profit entities, nor, for that matter, between paid and voluntary board members. Therefore, we have concluded that our interpretation of section 1124(a) of the Act is fully consistent with the language therein. Second, the corporate governing body of a provider or supplier usually exercises clear control over the latter. Even if certain members, such as volunteers, have less day-to-day control of the provider or supplier than other members, they can still (depending on the board's specific powers) influence the entity's operations and oversight, perhaps more so than certain individuals currently included within §§ 424.530(a)(2) and 424.535(a)(2), such as administrative personnel. Consequently, we believe that our proposed definition of ''director'' aligns with both the Act and our existing policy."

Diabetes Self-Management Training

CMS lists "diabetes self-management training" as a service that is high value and potentially underutilized in its list of underutilized services in the RFI within the CY 2023 Medicare PFS. To address this problem, CMS should act upon the NCCC recommendation to update the 2000 Medicare Quality Standards that govern diabetes self-management training (DSMT) and establish a process for ongoing review, updating, and revision, with broad input from persons and parties affected by these standards.[7]

NCCC recommends the following changes in CMS regulations related to DSMT to improve access and engage more people with diabetes:

1. Allow the initial 10 hours of DSMT to remain available beyond the first 12 months from diagnosis until fully utilized.
2. Allow for six additional hours (instead of two hours) of DSMT, if necessary.
3. Allow MNT and DSMT to be delivered on the same day.
4. Eliminate copays and deductibles (cost sharing) for DSMT.
5. Expand the types of physician providers who can refer for DSMT.
6. Allow community-based sites to provide DSMT.
7. Standardize the data collection required to simplify the process and ensure consistency across DSMT programs. CMS should ensure that all relevant partners including claims adjudicators follow a consistent approach throughout the audit and oversight processes to ensure better alignment with the purpose and scope of high-quality DSMT programs of all types and sizes.

To the extent that the above changes require Congressional action for statutory changes, the DAA urges CMS to communicate the need to stakeholders who can propose expeditious action by Congress to make these necessary changes, which are included in the Expanding Access to Diabetes Self-Management Training Act (S. 2203; H.R. 5804).

[7] See NCCC report Recommendation 6.1 on p.79.

Medical Nutrition Therapy

Minority populations have long faced chronic disease health disparities due to socioeconomic inequalities and reduced access to health care, healthy foods, and safe places to be active. These same groups are disproportionately impacted by COVID-19. The compounding impacts of systemic inequalities, food insecurity, reduced access to care and now COVID-19, underscore the need to provide equitable access to medical nutrition therapy in Medicare.

Currently, Medicare covers MNT for people with diabetes but does not cover this service for individuals with prediabetes, reducing the options that Medicare beneficiaries have for improving their health. MNT for individuals with prediabetes has been shown in numerous studies to decrease fasting blood glucose, body weight, blood pressure, and waist circumference for patients who received the intervention for at least 3 months.[8] A review of 66 programs by the Community Preventive Services Task Force found that programs that combined diet and physical activity counseling decreased diabetes incidence, and that the most intensive programs—primarily led by registered dietitian nutritionists in those studies—were the most effective at obtaining these outcomes.[9] [10] The DAA encourages CMS to review the body of literature on the effectiveness of MNT for treating prediabetes, and to cover MNT for Medicare beneficiaries diagnosed with prediabetes.

The Obesity-Diabetes Connection

Since most adults with prediabetes and type 2 diabetes are people with overweight or obesity, access to the full continuum of care to treat obesity is critical for addressing diabetes prevention, treatment, and care in Medicare beneficiaries. Even though clinical guidelines recommend treatment of obesity through intensive behavioral therapy (delivered by all modalities: community, online and telephonic), pharmacotherapy, and/or surgery, Medicare does not currently cover the full spectrum of interventions for obesity – interventions that are also important to curbing cases of prediabetes and type 2 diabetes. The COVID-19 pandemic has clearly shown and reinforced the urgent need to address diabetes and obesity, as these two conditions have been shown to be major risk factors for hospitalizations and death from COVID-19.

DAA members believe that CMS should update its regulations to allow access to the full continuum of obesity care available to patients. Current CMS guidance does not permit coverage for drugs that treat obesity under Part D, on the grounds that such drugs are excluded under the Part D statute as agents "used for anorexia,

---

[8] For a list of supporting sources, see
Parker, AR, Byham-Gray, L., Denmark, R., Winkle, PJ. 2014. The effect of medical nutrition therapy by a Registered Dietitian Nutritionist in patients with prediabetes participating in a randomized controlled clinical research trial. J Acad Nutr Diet 114(11): 1739-48.
Academy of Nutrition and Dietetics. 2014. Prevention of Type 2 Diabetes Evidence-Based Nutrition Practice Guideline. Evidence Analysis Library. http://andeal.org/topic.cfm?menu=5344&cat=5210
Raynor, H.A., Davidson, P.G., Burns, H., Hall Hadelson, M.D., Mesznik, S., Uhley, V., and Moloney, L. Medical nutrition therapy and weight loss questions for the Evidence Analysis Library Prevention of Type 2 Diabetes project: Systematic reviews. J Acad Nutr Diet. 2017; 117: 1578–1611.

[9] Balk, E.M., Earley, A., Raman, G., Avendano, E.A., Pittas, A.G., and Remington, P.L. Combined diet, and physical activity promotion programs to prevent type 2 diabetes among persons at increased risk: A systematic review for the Community Preventive Services Task Force. Ann Intern Med. 2015; 163: 437–451.
[10] Briggs Early, Kathleen et al. 2018. Position of the Academy of Nutrition and Dietetics: The Role of Medical Nutrition Therapy and Registered Dietitian Nutritionists in the Prevention and Treatment of Prediabetes and Type 2 Diabetes. Journal of the Academy of Nutrition and Dietetics, Volume 118, Issue 2, 343 – 353.

weight loss, or weight gain." CMS has held this policy for almost two decades, and in the meantime our scientific understanding of obesity and how to treat it have evolved substantially. The DAA believes that the CMS Part D policy which currently denies coverage of anti-obesity medications has the unintended effect of creating and perpetuating an unnecessary gap in access to an important standard of care. The DAA urges CMS to change its current policy to allow the full continuum of obesity treatments to patients.

Intensive Behavioral Therapy Is Underutilized

We call attention to the listing of intensive behavioral therapy as high value and potentially underutilized in its list of underutilized services in the RFI within the CY 2023 Medicare PFS. The goal of the Medicare IBT for Obesity benefit is to treat beneficiaries with obesity and reduce the rates of its comorbidities among older adults. As CMS has indicated, this benefit is not being utilized to its full potential, thus falling short of the goal. As of 2019, only 2.16% of the more than 7.6 million Medicare FFS beneficiaries with obesity received IBT for obesity. Research has shown that PCPs report a variety of barriers when it comes to providing weight and related nutrition counselling including inadequate time, training, and office space. Limiting the IBT for Obesity benefit to the primary care setting is a barrier that the DAA believes CMS must and can address in the CY 2023 Medicare PFS.

Conclusion

The DAA greatly appreciates this opportunity to provide comments to sections of the CY 2023 Medicare PFS that are concerned with underutilized services. We share a goal with CMS: innovative preventive services and programs for Medicare beneficiaries that address prevention of diabetes and improve treatment and care of diabetes to stabilize health in a cost-effective, health equitable manner. We stand ready to provide more information if requested and would be available for consultation as it relates to your questions or our comments. To contact the DAA, please connect with Hannah Martin, DAA co-chair (hmartin@eatright.org) or Kate Thomas, DAA co-chair (kthomas@adces.org).

Sincerely,

The undersigned members of the Diabetes Advocacy Alliance

Academy of Nutrition and Dietetics
American Medical Association
Association of Diabetes Care & Education Specialists
Black Women's Health Imperative
Endocrine Society
National Association of Chronic Disease Directors
National Kidney Foundation
Omada Health
Weight Watchers (WW)
YMCA of the USA