May 29, 2024

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: CMS–4207–NC

Dear Ms. Brooks La-Sure:

The American Heart Association (AHA) is pleased to respond to the Centers for Medicare and Medicaid Services' request for information (RFI) on Medicare Advantage (MA) Data, published in the *Federal Register*, vol. 89, no. 20, pp. 5907-5909 (January 30, 2024). We appreciate your staff's work on this RFI, especially given the many competing demands on the Agency's resources.

The American Heart Association is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. A shared focus on cardiovascular health unites our more than 40 million volunteers and supporters. Cardiovascular disease is the leading cause of mortality worldwide, and stroke ranks second globally. Even when those conditions don't result in death, they cause disability and diminish quality of life. The American Heart Association has invested more than $5 billion in research, making us the largest not-for-profit funding source for cardiovascular and cerebrovascular disease research after the federal government.

The connection between chronic disease and nutrition is undeniable. Our diets not only play a role in our risk of developing chronic diseases, but also can prevent, manage, and treat these diseases. Cardiovascular disease is the leading cause of death in the United States, and chronic diseases affected by nutrition including cardiovascular disease, stroke, and diabetes account for most of the nation's $4.3 trillion in annual health care costs.[1] Cardiovascular disease alone accounts for 12 percent of total U.S. health expenditures, considerably more than any other disease.[2] Heart disease and stroke cost the U.S. health care system $216 billion annually and cause $147 billion in lost job productivity.[3] Nutrition insecurity and unhealthy diets—characterized by a high intake of calories, sodium, added sugars, and saturated fat, and low intake of vegetables, fruits, and whole grains—significantly contribute to the development of cardiometabolic disease and chronic diseases more broadly. There are significant equity disparities as well, with higher rates of chronic disease mortality among those

[1] Martin AB, et al. National Health Expenditure Accounts Team. National health care spending in 2021: decline in federal spending outweighs greater use of health care: study examines national health care expenditures in 2021. Health Aff (Millwood). 2023; 42:6–17.
[2] Tsao CW, et al. Heart Disease and Stroke Statistics—2022 Update: A Report From the American Heart Association. Circulation. 2022;145:e153-e639.
[3] Centers for Disease Control and Prevention. Health and Economic Costs of Chronic Diseases. Accessed online April 15, 2024. https://www.cdc.gov/chronicdisease/about/costs/index.htm.

with low income, less education, and across different racial/ethnic populations. Black, Latino, and Native populations and low-income households, have higher rates of poor diet quality compared with the overall population.[4] There is a growing body of evidence that the health care system can be used to help patients access and consume healthy foods that can help address diet-related disease.

Food is medicine (FIM) refers to a food-based intervention for patients with a diet-related health risk or condition, to which they are referred by a health care provider, health care organization, or health insurance plan. Often these FIM interventions are coupled with medical nutrition therapy (MNT) and efforts to increase enrollment or participation in other federal and state safety net programs, and programs that address other social determinants of health (housing, education, transportation, social services, etc). FIM interventions include: medically tailored meals (MTMs), medically tailored groceries (MTGs), and healthy food prescriptions, such as produce prescriptions. It is important to note that FIM complements other critical efforts to address food and nutrition security needs, such as the Supplemental Nutrition Assistance Program (SNAP), Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), the charitable food system (food banks and pantries), among others, given that many patients living with or at risk of a diet-related health condition may also be experiencing food or nutrition insecurity.

The incidence of cardiovascular disease increases with age,[5] and the cost of treating cardiovascular disease puts a tremendous financial burden on the Medicare program.[6] [7] [8] Part of this financial burden will be shouldered by MA plans—private plans through which eligible Medicare beneficiaries can elect to receive their Medicare benefits. As of 2023, more than 50 percent of eligible beneficiaries were enrolled in MA plans.[9] MA plans are potentially well situated to address the needs of Medicare beneficiaries with cardiovascular disease, both through their ability to coordinate care for their enrollees (using integrated medical records and provider networks), and through their ability to provide supplemental benefits beyond the benefits covered by Medicare Parts A and B. Such benefits may include generalized services of interest to nearly all beneficiaries (e.g., dental, vision, and hearing benefits), but also items and services that have the potential to improve the health of beneficiaries with cardiovascular disease, such as FIM interventions.

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[4] Tsao CW, ibid.
[5] Rodgers JL, Jones J, Bolleddu SI, Vanthenapalli S, Rodgers LE, Shah K, Karia K, Panguluri SK. Cardiovascular Risks Associated with Gender and Aging. *J Cardiovasc Dev Dis.* 2019 Apr 27;6(2):19. doi: 10.3390/jcdd6020019. PMID: 31035613; PMCID: PMC6616540.
[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Downloads/HeartConditions_DataBrief_2017.pdf
[7] https://www.heart.org/-/media/Files/About-Us/Policy-Research/Fact-Sheets/Public-Health-Advocacy-and-Research/CVD-A-Costly-Burden-for-America-Projections-Through-2035.pdf
[8] https://meps.ahrq.gov/data_files/publications/st550/stat550.shtml?_gl=1*1hvzga*_ga*OTk5NjIzNDUwLjE3MDc5MjM3MTY.*_ga_1NPT56LE7J*MTcwNzkyMzcxNS4xLjEuMTcwNzkyMzg5Mi4wLjAuMA.
[9] https://www.medpac.gov/wp-content/uploads/2023/10/MedPAC-MA-status-report-Jan-2024.pdf

The link between diet and cardiovascular health has been long established.[10] [11] [12] In 2022, 71 percent of MA plans open to all eligible beneficiaries and 81 percent of plans open to beneficiaries dually-eligible for Medicare and Medicaid offered some type of meals, and 24 and 26 percent of these plans respectively offered nutritional/dietary benefits as part of their supplemental benefits.[13]

While the offering of specific types of supplemental benefits by MA plans can be documented through their bids and enrollee information and marketing materials, the actual uptake of these benefits is unknown. Largely for purposes of risk-adjusting Medicare payments to MA plans, CMS requires MA plans to submit "encounter records" which the agency describes as "the data necessary to characterize the context and purposes *of each item and service provided to a Medicare enrollee*" [emphasis added].[14] However, until now, Medicare has *not* required plans to submit encounter records documenting their provision of supplemental benefits.[15] Therefore, it is currently not possible to document the supplemental benefits that MA enrollees actually use; by implication, neither is it possible to examine the impact of any given category of supplemental benefits on the health status and outcomes of MA plan enrollees.

In this RFI, CMS specifically requests comments on collecting data on "the cost and utilization of different supplemental benefits." The American Heart Association strongly supports such data collection. Subsequent to the publication of the RFI, AHA was particularly encouraged to see the Agency's February 21, 2024, HPMS memorandum "Submission of Supplemental Benefits Data on Medicare Advantage Encounter Data Records."

MA plans have the flexibility under current statute to innovate in the delivery of care in ways that traditional fee-for-service (FFS) Medicare cannot. The current level of rebate dollars (double the level it was five years ago) would seem to provide MA plans with sufficient financial resources to invest in interventions offered through supplemental benefits (medically tailored meals and dietary services) that have the demonstrated potential to improve the cardiovascular health of their enrollees. Indeed, as evidenced through their benefit offerings, many MA plans appear to recognize the potential benefits from such interventions. However, without detailed, standardized information on the types of interventions conducted under the auspices of a FIM philosophical construct, the effectiveness of such interventions cannot be assessed. The absence of

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[10] https://www.bswhealth.com/blog/food-as-medicine-why-diet-is-the-foundation-for-a-healthy-heart#:~:text=The%20short%20answer%3A%20Absolutely.,or%20worse%2C%20a%20heart%20attack.

[11] Volpp KG, Berkowitz SA, Sharma SV, Anderson CAM, Brewer LV, Elkind MSV, Gardner CD, Gervis JE, Harrington RA, Herrero M, Lichtenstein AH, McClellan M, Muse J, Roberto CA, Zachariah JPV; on behalf of the American Heart Association. Food Is Medicine: a presidential advisory from the American Heart Association. *Circulation*. 2023;148:1417–1439. doi: 10.1161/CIR.0000000000001182

[12] Yang Y, Chan SW, Hu M, Walden R, Tomlinson B. Effects of some common food constituents on cardiovascular disease. *ISRN Cardiol*. 2011;2011:397136. doi: 10.5402/2011/397136. Epub 2011 Jun 16. PMID: 22347642; PMCID: PMC3262529.

[13] Medicare Payment Advisory Commission. 2023. Rep*ort to the Congress: Medicare and the Health Care Delivery System*. Washington DC: MedPAC.

[14] https://www.csscoperations.com/internet/csscw3_files.nsf/F/CSSCED_Submission_Processing_Guide_20201009.pdf/$FILE/ED_Submission_Processing_Guide_20201009.pdf

[15] MedPAC 2023 *op. cit*.

such information in MA is a narrower instance of the broader need for data to evaluate the effectiveness of such interventions.[16]

We support the new CMS requirement that MA plans report detailed encounter records for supplemental benefits offered to (and taken up by) their enrollees. The example provided in the memorandum related to food, however, is only for pre-funded payment cards. CMS states in the memorandum that, "CMS strongly encourages MA organizations to report each use of an allowance or payment card and the items or services being paid for with that allowance or payment card." For pre-funded payment cards, MA plans should also document the total value of the card and duration or frequency (*e.g.,* issued monthly over one year), and the reach or scope of the retailers participating in the program.

Plans should also be required to document the provision of different FIM interventions (above and beyond pre-funded payment cards) through encounter data: each instance of medically tailored meals, medically tailored groceries, healthy food prescriptions, produce prescriptions, and other dietary and nutritional interventions offered via supplemental benefits that have their own corresponding codes. We also encourage CMS to issue memoranda for MA plans participating in the Value-Based Insurance Design (VBID) model to adopt these codes and provide this level of information given that many of these plans are offering pre-funded payment cards for food as a supplemental benefit. Current CMS regulations permit the reporting of S-codes on the standard encounter record format, and we suggest that existing HCPCS codes such as S5170 and S9977 could form the initial basis for such reporting. Similarly, to the extent plans are offering dietary and nutrition planning and counselling as supplemental benefits, CPT codes 97802 (individual nutrition therapy, initial assessment), 97803 (individual nutrition therapy), 97804 (group nutrition therapy), and HCPCS codes S9470 (nutritional counseling, dietitian visit), and G0270 / G0271 (medical nutrition therapy following a change in patient condition) could serve as the foundation code set for such reporting.[17] CMS could evaluate the applicability of other codes for items and services related to medically tailored meals, medically tailored groceries, healthy food prescriptions, and produce prescriptions, through notice-and-comment rulemaking, as warranted. Such granularity will help determine the impact of different FIM interventions for different patient populations.

Further, we encourage CMS to provide technical assistance and encourage plans to transition to these new requirements. MA organizations must submit data for supplemental benefits in accordance with these new instructions beginning with contract year (CY) 2024 dates of service, however, CMS can encourage MA organizations to submit this new encounter data as soon as possible for CY 2024 dates of service (01/01/2024 through 12/31/2024).

Over the longer-term, we urge CMS to revise the Medicare Advantage Quality Bonus Program (QBP) to include more measures that focus on cardiovascular-related

[16] Volpp, KG, *et al.* 2023 *op cit.*
[17] CPT (current procedural terminology) codes copyright American Medical Association.

outcomes. Currently, clinical measures compose only 27 percent of the weighted share of MA "star ratings" under the MA QBP.[18] Of the 16 current measures in the clinical quality group, only three (monitoring physical activity, controlling blood pressure, and statin therapy for patients with cardiovascular disease) are related to cardiovascular health, and two of these are process measures (or intermediate outcomes measures at best). We recommend that CMS work with measure development organizations to develop measures more directly focused on cardiovascular health outcomes, so that the efficacy of targeted interventions provided through supplemental benefits can be more comprehensively assessed. The American Heart Association stands ready to assist CMS in the identification of appropriate measures in this category for use in the MA QBP.

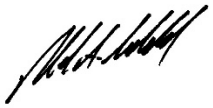
Lastly, we support CMS' goal of making these data publicly available. We believe they will be invaluable for stakeholders, clinicians and policymakers to more definitively assess the efficacy of MA plans' FIM interventions, and for Medicare beneficiaries with cardiovascular disease looking for information to help select a plan with the greatest success in managing their conditions.

About Health Care by Food™ (HCXF)
In conjunction with the White House Conference on Hunger, Nutrition, and Health in 2022, the American Heart Association and The Rockefeller Foundation launched the Health Care by Food initiative to strengthen the evidence base for FIM. Our vision is to accelerate a future in which millions of patients receive the benefit of a more holistic approach to diet and health, health care professionals and practitioners know how FIM programs can help prevent and manage disease, and payors have sufficient, objective cost-effectiveness evidence for reimbursing FIM programs. The initiative will provide the large-scale clinical evidence required to help identify, support and implement the most viable FIM strategies as a covered benefit through public and private health insurance.

Launched in Spring 2023, the HCXF initiative is made up of over 55 leading researchers across the country in diverse academic fields, guided by the support of dozens of experts who comprise nine volunteer task forces that are examining issues ranging from health equity and common measures for FIM, community engagement and implementation science, behavioral science, cost effectiveness, human-centered design, and evaluation of the Medicaid waivers, among other issues. Already the HCXF initiative has funded nearly $8 million in 19 research grants that will test the clinical effectiveness of different FIM interventions in diverse patient populations with diabetes, hypertension, cardiovascular disease, and high-risk pregnancy. The initiative is also funding an implementation analysis of the high and low redemption rates in the Gus Schumacher Nutrition Incentives Program (GusNIP) program through the Gretchen Swanson Center for Nutrition. Together, these grants involve researchers from more than 20 academic institutions, 27 community-based organizations, and a number of national corporations with participation throughout much of the United States. These promising short-term and smaller studies will inform larger, scalable research studies.

[18] MA plans with a "star rating" of four stars or higher are eligible for additional quality bonus payments from Medicare.

Sincerely yours,



Mark Schoeberl
Executive Vice President, Advocacy
American Heart Association

The American Heart Association appreciates the opportunity to respond to this Request for Information. If we can be of further assistance, please do not hesitate to contact Colin Schwartz, MPP, Senior Advocacy Advisor, Health Care by Food™, American Heart Association at Colin.Schwartz@heart.org.