CENTER *for* HEALTH LAW
and POLICY INNOVATION
HARVARD LAW SCHOOL

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Seema Verma
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-2018-0154
Hubert H. Humphrey Building
200 Independence Ave SW
Washington, DC 20201

Dear Administrator Verma,

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) recent Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter (CMS-2018-0154). We commend CMS on the proposed changes to expand Medicare Advantage (MA) supplemental benefits, and we are eager to provide recommendations regarding how CMS can maximize the impact of these changes by encouraging coverage of key nutrition interventions.

CHLPI advocates for legal, regulatory, and policy reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. For a number of years, CHLPI has worked with community-based nutrition organizations across the country to support the integration of Food is Medicine interventions into the delivery and financing of health care. Food is Medicine interventions are a spectrum of services that recognize and respond to the critical link between nutrition and chronic illness. These interventions consist of healthy foods that are tailored to meet the specific needs of individuals living with or at risk for one or more health conditions affected by diet.

The expansion of supplemental benefits for individuals living with chronic illnesses provides an important opportunity to improve care by integrating Food is Medicine interventions into MA plans. Food is Medicine nutrition interventions, including the provision of medically-tailored meals,[1] medically-tailored food,[2] and produce prescriptions or vouchers,[3] have been shown to

[1] **Medically-tailored meals** are delivered to individuals living with severe illness through a referral from a medical professional or health care plan. Meal plans are tailored to the medical needs of the recipient by a Registered Dietitian Nutritionist (RDN), and are designed to improve health outcomes, lower cost of care and increase patient satisfaction.
[2] **Medically-tailored food** interventions are bags/boxes/packages of food designated by an RDN or other medical professional as an appropriate part of a treatment plan for an individual with a defined medical diagnosis.
[3] **Produce prescription** programs are vouchers distributed by medical professionals or health care plans as part of a prevention or treatment plan for a defined medical diagnosis. These vouchers are then redeemed at retail grocers or farmers markets for free or discounted produce.

improve patient outcomes and reduce health expenditures, particularly for chronically ill populations. As a result, they are a natural fit for the new Special Supplemental Benefits for the Chronically Ill (SSBCI) program.

For these reasons, we again applaud CMS's proposed changes that would provide MA plans greater flexibility to cover nutrition services via the SSBCI program. However, we recommend that CMS make the following clarifications:

1) **We urge CMS to expand access to medically-tailored meals (MTMs) more broadly throughout Medicare.**
2) **Within the SSBCI Program, we urge CMS to:**
    a. **Encourage MA plans to include Food is Medicine interventions in their SSBCI packages;**
    b. **Allow for flexibility in the definition of "chronic condition;"**
    c. **Prohibit the use of financial criteria when determining SSBCI eligibility; and**
    d. **Prohibit reliance on community-based organizations to assess SSBCI eligibility.**

1) We urge CMS to expand access to medically-tailored meals (MTMs) more broadly throughout Medicare.

Chronic Illness and MTMs

Chronic illness is on the rise for older adults: approximately 80% of older adults have at least one chronic disease, and 77% have at least two.[4] These chronic conditions ultimately drive health care costs in the United States, as individuals with chronic health conditions account for approximately 90% of all health care spending.[5]

Medically-tailored meals (MTMs) are a low-cost, high-impact intervention capable of meeting the nutritional needs of individuals living with these conditions. An individual can receive a medically-tailored diet for six months for the same cost as just one night's stay in a hospital. As a result, research shows that the return on investment for MTMs is clear and almost immediate – with results available in as little as 30 days. In a 2018 study, researchers found that providing MTMs to patients dually eligible for Medicare and Medicaid reduced the need for costly medical interventions.[6] Specifically, as compared to matched controls, dually eligible patients receiving MTMs experienced a 70% reduction in emergency department visits, a 52% reduction in inpatient admissions, and a 72% reduction in emergency transportation events. Overall, the

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[4] *See Healthy Aging Facts*, NATIONAL COUNCIL ON AGING, https://www.ncoa.org/news/resources-for-reporters/get-the-facts/healthy-aging-facts/ (last visited Feb. 25, 2019).
[5] *See* Christine Buttorff et al., *Multiple Chronic Conditions in the United States*, RAND CORPORATION at 20 (2017), *available at* https://www.rand.org/content/dam/rand/pubs/tools/TL200/TL221/RAND_TL221.pdf.
[6] Berkowitz SA, Terranova J, Hill C, Ajayi T, Linsky T, Tishler LW, DeWalt DA, *Meal Delivery Programs Reduce The Use Of Costly Health Care In Dually Eligible Medicare And Medicaid Beneficiaries*, 37(4) HEALTH AFFAIRS 535-42 (Apr. 2018).

MTM intervention resulted in a 16% net reduction in health care costs, saving $220 per patient per month.

Recent studies across the nation have shown similar results. A study conducted in Philadelphia showed a 28% drop in average monthly health care costs for Medicaid managed care patients battling life-threatening illness who received MTMs and Medical Nutrition Therapy (MNT).[7] When compared to similar patients who did not receive these services, study participants experienced 50% fewer hospital admissions and were 23% more likely to be discharged to their homes rather than another facility. In a retrospective cohort analysis, an MTM program in Denver similarly recorded a 24% decrease in health care costs for patients enrolled in their services who were diagnosed with congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), or diabetes.[8] Finally, a study conducted in San Francisco found that receipt of MTMs increased adherence to antiretroviral therapy (from 47-70% adherence) for individuals living with HIV and significantly decreased diabetes distress for diabetic patients.[9]

Taken together, this growing body of research indicates that providing access to MTMs is an effective strategy for meeting the health care goals of improving health outcomes, lowering costs, and improving patient satisfaction, especially for our country's sickest individuals.

Expanding Coverage of MTMs throughout Medicare

Given the proven potential of MTMs to significantly improve the lives of Medicare patients coping with chronic illness, we applaud CMS's decision to specifically allow MA organizations to include "home-delivered meals (beyond the current allowable limited basis)" in their SSBCI package. This decision creates much-needed flexibility for MA plans to maximize delivery of MTMs to some of their sickest enrollees.

However, the vast majority of Medicare recipients will not have access to SSBCI and will therefore continue to have limited or no access to MTMs. 66% of Medicare enrollees participate in Traditional Medicare (Medicare Parts A and B), which currently provides no coverage for MTM services. We therefore urge CMS to investigate and leverage all potential opportunities to use its administrative authority to extend coverage for MTMs to the Traditional Medicare population. By doing so, CMS can more broadly and effectively improve the lives of Medicare enrollees struggling with chronic illness and reduce associated costs.

Additionally, we urge CMS to use the momentum from recent expansions of supplemental benefits to allow broader coverage of MTMs for the general MA population. While MA plans have historically been allowed to provide some coverage of meals as part of their supplemental

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[7] Jill Gurvey et al., *Examining Healthcare Costs Among MANNA Clients And A Comparison Group*, 4 J. OF PRIMARY CARE & COMMUNITY HEALTH, 311-312 (2013).

[8] *Small Intervention, Big Impact: Health Care Cost Reductions Related to Medically Tailored Nutrition*, PROJECT ANGEL HEART (June 2018), *available at* https://view.publitas.com/project-angel-heart/whitepaper-small-intervention-big-impact/page/1.

[9] Palar, K., Napoles, T., Hufstedler, L.L. et al., *Comprehensive and Medically Appropriate Food Support Is Associated with Improved HIV and Diabetes Health*, 94 J. URBAN HEALTH 87-99 (2017).

benefit packages, these programs have been subject to narrow time and population limits.[10] In 2018, CMS took the important step of broadening its definition of "primarily health related," thereby broadening the scope of supplemental benefits for all MA enrollees. This new definition reinforced CMS's interest in supporting access to services that "ameliorate the functional . . . impact of injuries or health conditions, or reduce[] avoidable emergency and healthcare utilization."[11] Given the proven ability of MTMs to meet both of these goals, we hope that CMS will revisit its current restrictions on the provision of meals and support broader coverage when such meals are medically-tailored.

2) Within the SSBCI Program, we urge CMS to:

a. Encourage MA plans to include Food is Medicine interventions in their SSBCI packages

Again, CHLPI firmly applauds CMS's decision to highlight nutrition interventions in the language of the Draft Call Letter. In particular, we commend CMS's statement that SSBCI may include home delivered meals (beyond the current allowable limited basis) as well food and produce. Notably, Food is Medicine interventions can have a *particularly* powerful impact on patient health outcomes and costs. For example:

Medically-Tailored Meals:

In the 2018 study of dual eligible patients described above, researchers found that both non-tailored and medically-tailored meals resulted in decreased health care utilization and net savings when compared to a control group. However, the net savings associated with MTMs were significantly higher. While the provision of non-tailored meals resulted in net savings (including the cost of meals) of $10 per patient per month, the provision of MTMs resulted in net savings of $220 per patient per month.[12]

Medically-Tailored Food & Produce Prescriptions

Medically-tailored food and produce prescription programs can have a similarly powerful impact on health outcomes for individuals living with chronic illness. For example, a recent pilot study found that medically tailored food boxes:

- Improved mean HbA1c from 8.11% to 7.96% for diabetic food pantry clients;
- Improved mean HbA1c from baseline 9.52% to 9.04% for food pantry clients with very poor glycemic control (>9%); and

[10] Medicare Managed Care Manual, §30.3, at 40.
[11] *See Reinterpretation of "Primarily Health Related" for Supplemental Benefits*, CENTERS FOR MEDICARE & MEDICAID SERVICES (April 27, 2018).
[12] Berkowitz SA, Terranova J, Hill C, Ajayi T, Linsky T, Tishler LW, DeWalt DA, *Meal Delivery Programs Reduce The Use Of Costly Health Care In Dually Eligible Medicare And Medicaid Beneficiaries*, 37(4) HEALTH AFFAIRS 535-42 (Apr. 2018).

- Reduced diabetes distress, measured on a scale of 1-6, from 3.1 to 2.7.[13]

Similarly, a 2017 study of a produce prescription program found:

- Improved mean HbA1c from 9.54% to 8.83% when participants were provided with $10/week for up to four weeks to spend on fresh fruits and vegetables.[14]

Given the important role that these interventions have been shown to play in addressing chronic illness, we recommend that CMS look for opportunities to highlight Food is Medicine interventions, in particular, in the Final Call Letter and any additional guidance that CMS provides regarding the program. By doing so, CMS can maximize the impact of the SSBCI program by raising awareness among MA plans regarding Food is Medicine interventions and encouraging plans to consider coverage for patients who would benefit from them.

b. Allow for flexibility in the definition of "chronic condition;"

CHLPI supports CMS's proposal to define chronic illness based upon the list of conditions outlined in part 16b of the Medicare Managed Care Manual,[15] but also recognizes that some widespread and highly impactful conditions are missing from the current list. For example, the current list does not include: osteoporosis, Alzheimer's disease, chronic kidney disease, chronic obstructive pulmonary disease (COPD), Down syndrome (or other developmental disorders in adults), or obesity. Going forward, therefore, CHLPI encourages CMS to take additional steps to allow for flexibility and community input regarding how chronic conditions are defined in order to ensure that SSBCI are available to a broad spectrum of chronically ill beneficiaries.

In Calendar Year (CY) 2020, we recommend that CMS permit MA plans that wish to extend SSBCI to populations beyond those on the current list to propose these additions in their annual benefit package submission. CMS would retain the authority to deny these additions, but plans would have the opportunity to justify their proposal and potentially be approved for coverage.

By CY 2021, CMS has proposed creating a technical advisory panel to approve additions to the current list of chronic conditions. We support this proposal and recommend that in forming the technical advisory panel, CMS should include experts across a broad range of chronic illnesses. Additionally, we recommend that the panel include representation from community-based organizations that deliver services, such as Food is Medicine interventions, that will be covered in the SSBCI program (and/or experts with clearly demonstrated knowledge of these programs). This will ensure that the panel leverages the experience and expertise of these organizations to cover conditions where there is known potential for SSBCI to improve care.

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[13] Hilary K. Seligman et al., *A Pilot Food Bank Intervention Featuring Diabetes-Appropriate Food Improved Glycemic Control Among Clients in Three States*, 34(11) HEALTH AFFAIRS (2015).
[14] Richard Bryce et al., *Participation in a farmers' market fruit and vegetable prescription program at a federally qualified health center improves hemoglobin A1C in low income uncontrolled diabetics*, 7 PREVENTIVE MEDICINE REPORTS (2017).
[15] Medicare Manual Managed Care Manual, 16b §20.1

Finally, we recommend that CMS establish a well-defined, transparent process through which plans and other groups or individuals can recommend changes to the technical advisory panel. Having this formalized process will ensure that the priorities of individual members of the technical advisory panel do not skew the list in any one direction and allow the panel to leverage existing community knowledge to improve the SSBCI program.

c. Prohibit the use of financial criteria when determining SSBCI eligibility

In the Draft Call Letter, CMS requests comment on whether to allow MA plans to consider other criteria, such as financial need, when determining permissible SSBCI. CHLPI understands why, given limitations on plan resources, CMS is tempted to allow this practice. However, we firmly advise against it. First, adding a means tested element to the SSBCI program could create feasibility issues, and opportunities for error, for any plans and providers who are not currently accustomed to collecting this sort of information.

Second, we know from years of working with organizations focused on treating chronically ill populations that these conditions, and their impact on patient quality of life, cross all financial boundaries. Individuals living with chronic conditions, and especially those living with multiple chronic conditions, are already juggling a variety of complex disease management requirements which can make individual activities, such maintaining a proper diet, more difficult, even for patients with higher incomes.

Furthermore some SSBCI services are so complex that individuals could not independently recreate them, regardless of income. MTMs, for example, are designed by Registered Dietitian Nutritionists (RDNs), often to meet the requirements of multiple medical conditions. As a result, even high income individuals could not feed themselves in the same way outside of an MTM program. CHLPI therefore urges CMS to prohibit means testing, to ensure that SSBCI remain available to all members that can benefit from them.

d. Prohibit reliance on community-based organizations to assess SSBCI eligibility.

Finally, the Draft Call Letter states that community-based organizations "can also help determine whether an individual meets the eligibility requirements for SSBCI." We urge CMS to reconsider or more firmly limit this position. If MA plans are allowed to ask community-based organizations to assist in eligibility determinations, plans may attempt to rely on these organizations to assess large swaths of their patient population. Many community-based organizations lack the staff capacity and proper infrastructure to perform these types of broad assessments, and may open themselves up to new liabilities if they attempt to do so. To avoid these unintended consequences, we recommend that CMS prohibit MA plans from relying on community-based organizations to assess SSBCI eligibility.

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We applaud CMS's expansion of supplemental benefits to include Food is Medicine programs and would be happy to work with CMS to further address any of the comments provided above. Please contact Sarah Downer at sdowner@law.harvard.edu with any questions.

Sincerely,

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on behalf of

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