Implementation Considerations for Medically Tailored Meals

Executive Summary

The Food Is Medicine Coalition and the Tufts Friedman School for Nutrition Science and Policy respectfully submit the following information in response to the Centers for Medicare and Medicaid Services (CMS) and the Center for Medicare and Medicaid Innovation's (CMMI) inquiry about the following areas of Medically Tailored Meal (MTM) Intervention Implementation: Target Population and Duration for the MTM Intervention; Implementation Opportunities and Challenges; Measurement and Evaluation; and Opportunities to Pilot and Evaluate MTMs through Existing CMS Innovation Center Models. Key points from the four sections of this memo appear in this Executive Summary, with further detail provided in the pages that follow.

An important overarching, conceptual point is that the Medically Tailored Meal Intervention (MTMs) is a disease treatment that fulfills a prescribed diet, targeting nutrition as a determinant of health. MTMs are not primarily designed to address social determinants of health (SDOH), nor an intervention to target food security or other health related social needs (HRSNs), though, of course, access to MTMs can address all of these needs.

MTMs are meals delivered to individuals of all ages living with severe or complex chronic illness(es) and activities of daily living (ADLs) limitations, as deemed necessary by a healthcare professional. Meal plans are tailored to the medical needs of the recipient by a Registered Dietitian Nutritionist (RDN) who provides nutrition assessment, reassessment, and monitoring, as well as medical nutrition therapy (MNT) and nutrition counseling as indicated for the recipient as part of the MTM intervention. The nutrition quality of MTMs are governed by the FIMC MTM Nutrition Standards which are based on dietary guidelines for specific health conditions. MTMs are designed to improve health outcomes, lower the cost of care, and increase client satisfaction.

I. Target Population and Duration for the MTM Intervention

- The MTM intervention should generally be tested in populations that:
  - have one or more severe or complex chronic condition(s) (e.g., poorly controlled diabetes, heart failure, myocardial infarction, cancer, chronic kidney disease or end stage kidney disease, and/or HIV, among others);
  - have at least one limited activity of daily living; and
  - experience high burdens of disability, illness, and healthcare utilization.
  - NOTE: Income and food security criteria are not necessary for eligibility, but often accompany the above criteria. Additional populations may also benefit from MTMs
- The recommended density and duration for the MTM intervention is at least 10 (and up to 21) meals per week for a minimum of six months and longer with appropriate reauthorization, with a follow-up evaluation of at least 12 months.
- The published research indicates that service duration for longer than six months may be necessary to durably improve health outcomes and result in reductions in healthcare utilization. On April 26, 2023, FIMC sent a letter to CMS with feedback on recently released guidance that limits MTM service duration to 6 months. That letter is attached as Appendix A.

II. Implementation Opportunities and Challenges

- On April 24, 2023, stakeholders sent a letter to CMS with feedback and recommendations regarding section 1115 demonstrations piloting nutrition interventions, informed by a survey

of on-the-ground implementers, participants, and evaluators of these demonstrations. This letter addresses Legal and Regulatory Barriers, Practical Barriers, and Infrastructure Funding and Support and is attached as Appendix B.

- Changing or unreliable regulations, eligibility mandates, and inconsistent funding streams make it difficult for plans and service providers to offer MTMs for a significant number of members or to sustain the program long-term; all of which negatively impacts our ability to evaluate these partnerships effectively.
- Like prescription medications, which are only effective if they are taken, MTMs are only effective if they are consumed, making nutritional quality – and taste - especially important. The composition and quality of the MTM intervention is described in the Food Is Medicine Coalition (FIMC) MTM Nutrition Standards.
- A recent national survey led by Tufts faculty identified strong interest in Food is Medicine interventions in healthcare. Key findings are available in this section, but 70% of respondents somewhat or strongly agreed that the healthcare system should help pay for delivery of healthy groceries or meals to homes of patients with appropriate medical conditions.

III. Measurement and Evaluation

- A multi-state demonstration is needed within CMS and/or CMMI—which could be designed and implemented using several existing pilot authorities—to robustly test the effects of MTM. This call for demonstration projects has the support of Congress, the Biden-Harris Administration, and the Food Is Medicine community.
- The Aspen Institute's Food is Medicine Research Action Plan details field-wide recommendations on research process and design and should be used as a guide.
- Demonstrations should test with and without scaling the MTM intervention to household size (i.e., scaling to household size indicates that meals would be provided for other individuals like caregivers, dependents in the same household as the primary recipient)
- Key utilization outcome measures that have already been demonstrated but should be expanded upon are hospital, emergency room, and nursing home admissions; net healthcare costs; and medication adherence.
- Key patient-centered outcome measures should include food security, nutrition security, malnutrition, self-reported physical and mental health, change in activities of daily living, beneficiary satisfaction and quality of life. Studies should evaluate the outputs of the RDNs Nutrition Care Process and track disease-specific markers.
- NOTE: FIMC will be responding to NIH's Request for Information (RFI): Food is Medicine Research Opportunities and plans to submit our response to the RFI to this group as well.

IV. Opportunities to Pilot and Evaluate MTMs through Existing CMS and CMS Innovation Center Models

- We encourage CMS to use existing models – or targeted expansions of these models - to evaluate MTMs and thereby address any gaps that CMS currently sees in the evidence base.
- Models include:
    - Accountable Health Communities 2.0
    - Accountable Care Organizations
    - Disease-specific CMS Innovation Models
    - SSBCI Data in Medicare Advantage

We appreciate CMS and CMMI's recognition of the importance of Food is Medicine and your attention to addressing the need for Medically Tailored Meals in Medicaid, CHIP, and Medicare. Thank you for your consideration of our perspective and recommendations regarding this important framework as you plan future innovations at CMS.

I. Target Population and Duration for the MTM Intervention

Target Population

Medically tailored meals (MTM) are a clinical intervention that answer the nutritional needs of the individuals experiencing severe or chronic complex illness. The majority of individuals who receive MTMs live with co-morbid conditions and experience activities of daily living limitations. FIMC clients often require the assistance of family or caregivers and have complex dietary needs and restrictions due to their chronic health condition(s) or acute illness. As a result, these individuals may not be able to access other emergency food support systems available in their communities because of accessibility issues, age or income restrictions, or the complexity of the nutrition that they require. An increasing evidence base suggests that MTMs can be efficacious alongside treatment for a variety of conditions and situations, such as for those recently exiting the hospital and needing to stabilize at home, for pregnant and post-partum persons, or for those living with behavioral or mental health diagnoses.

Food insecurity and income screening are not necessarily predictive of the need for MTM, whereas a positive malnutrition screen may be. The MTM intervention has been associated with reduced hospitalizations and decreased emergency department visits and should be offered to populations that have experienced both – the high-need, high-cost beneficiaries in our healthcare system. Using Clinical Risk Groups (CRGs) to target those who need the service is another way to pinpoint need,[1] as is targeting Dual Medicare/Medicaid eligibles with service as a particularly high-need population.

The MTM intervention began as a community response and continues to be largely supported by philanthropy across the country. However, the intervention has always been connected to the medical care continuum. Referrals to FIMC agencies for the intervention may come from a variety of community, healthcare, and private sources, though they may require verification and documentation of health condition(s) or other relevant data, to assess an individual's eligibility to receive MTM services. When delivered as part of a healthcare engagement, MTM services are ordered for the purposes of treating an enrollee's health condition and authorizations are sent to the FIMC agency directly. The MTM provision requires that each enrollee goes through a nutrition assessment conducted by a Registered Dietitian Nutritionist (RDN) which results in a meal plan that meets their specific health needs.

Examples of individuals for whom MTM would be indicated	Examples of individuals for whom MTMs would historically not be indicated, but for whom other nutrition interventions may be appropriate
An individual with HIV and end stage kidney disease	An individual with asthma who occasionally has attacks but manages their condition with medication
An individual with severe, unmanaged diabetes that has resulted in complications limiting ADLs	An individual with Type 2 diabetes, who is not managing their blood sugar well, but who is able to participate in Diabetes Self-Management Education or Training (DSME/DSMT) and receive medical nutrition therapy
An individual with heart failure, edema, chest pain and shortness of breath	An individual with hypertension who can still ambulate and shop and cook for themselves.
An individual who is undergoing active treatment for cancer via chemotherapy and radiation	An individual for whom cancer is in remission and now needs to cook and eat right for their illness
An individual with ALS who has trouble chewing, swallowing and preparing meals	An individual with an autoimmune disorder that requires healthful eating

Table 1: Target population examples

[1] https://multimedia.3m.com/mws/media/7658330/3m-crgs-measuring-risk-managing-care-white-paper.pdf

Density and Duration of the Intervention

MTMs can be used in a variety of capacities to address illness through the lens of nutrition, control and manage medications and side-effects, help recipients remain in their homes, and prevent conditions from worsening. The duration of the intervention is variable and should be based on the individual's needs as determined by an RDN, but for those living with complex, chronic conditions, most MTM agencies provide at least 10 meals per week (with the option to provide full nutrition of 21 meals/week) and most research has been conducted at this density of service, which appears necessary to see the positive outcomes evidenced.

While health improvements can begin to accrue immediately with MTM, the published research provides a strong signal that service duration for longer than six months may be necessary to durably improve health outcomes and result in reductions in healthcare utilization. A recent study found that the average time individuals received medically tailored meals in previous studies with documented positive impacts on healthcare utilization was 8 months, with some individuals receiving meals for 12-24 months.[2] In fact, on April 26, 2023, the Food Is Medicine Coalition sent a letter to CMS with feedback on recently released guidance that limits MTM service duration to 6 months, asking that it be reconsidered in light of the evidence. **That letter is attached as Appendix A.**

Shorter Term and Episodic Receipt of MTMs

MTMs are increasingly being used in the short term, such as post-discharge access to the MTM intervention after a hospitalization to aid in transition to home and minimize the risk of rehospitalization. Further, the MTM intervention is being used in hospital-at-home programs to supply the disease-specific nutrition needs of patients needing acute-level care in their homes, rather than in a hospital setting.

MTMs are also indicated for a variety of conditions that are episodic in intensity. Provision of services to a person undergoing treatment for cancer is a good example. Populations with cancers experience impairments including cancer cachexia, fatigue, nutrition impact symptoms, and malnutrition.[3] Furthermore, chemotherapy and radiation can decimate appetite. It is imperative that cancer patients have access to specialized diets to allow individuals to better tolerate treatment-related side effects, maintain weight, and recover faster. After active treatment and cancer remission, individuals often regain strength and can return to shopping and cooking for themselves with the proper nutrition education. Should the cancer return, then the client can resume MTM services.

Role of the RDN in Assessing Treatment Duration

The RDN's role in assessment is an established medical protocol. The nutrition assessment is one element of the Nutrition Care Process, which is a standardized approach to care implemented by Registered Dietitian Nutritionists when providing medical nutrition therapy, as outlined in best practice guidelines by the Academy of Nutrition and Dietetics.[4]

During nutrition assessment, the RDN collects, classifies, and synthesizes important and relevant health data needed to identify nutrition-related problems and their causes. Nutrition Reassessment is to identify whether previously collected information has changed or remained the same. Reassessment then allows the RDN to determine if previous nutrition problems have been resolved or changed, or if new nutrition problems exist and whether the treatment – in this case MTMs –

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[2] Kurt Hager et al., Association of National Expansion of Insurance Coverage of Medically Tailored Meals with Estimated Hospitalizations and Health Care Expenditures in the US, 5 JAMA Network Open e2236898 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797397 (doi:10.1001/jamanetworkopen.2022.36898).

[3] https://www.nationalacademies.org/our-work/diagnosing-and-treating-adult-cancers see chapter 9; malnutrition source: https://pubmed.ncbi.nlm.nih.gov/31359189/ and https://www.cancer.gov/about-cancer/treatment/side-effects/appetite-loss/nutrition-hp-pdq

[4] Academy of Nutrition and Dietetics, "Definition of Terms List," Eat Right, February 2021, p. 49, www.eatrightpro.org/-/media/files/eatrightpro/practice/academy-definition-of-terms-list-feb-2021.pdf

should continue. For successful interventions, the knowledge and expertise of trained RDNs should be leveraged.

When the nutrition assessment reveals nutrition problems and unaddressed medical issues, there is an ethical imperative for the RDN to intervene, or to refer individuals for follow up care. It is critical to highlight that several populations do not have evidence-based nutrition care (i.e., medical nutrition therapy, or MNT) outside the context of a philanthropic MTM provider organization because of a lack of insurance benefits or coverage for their conditions. The use of the MTM intervention in Medicare and Medicaid could close important gaps in nutrition care. The Medicare MNT benefit (Part B) covers medical nutrition therapy for diabetes, chronic kidney disease, and three years post kidney transplant only. Some states have benefits for MNT in Medicaid programs but may not include the diagnoses indicated for MTMs.

The Evidence – National Modelling of Population, Duration and Savings

A recent study conducted by Tufts investigated the potential impact of national expansion of insurance coverage of MTMs. The researchers estimated one and ten-year potential changes in annual hospitalizations, potential changes in annual health care expenditures, and overall policy cost-effectiveness associated with national MTM coverage for U.S. patients with diet-related disease (one or more diet-sensitive conditions -- diabetes, congestive heart failure, myocardial infarction, other heart disease, emphysema, stroke, nonmelanoma cancer, chronic kidney disease, and HIV infection) and limited instrumental activities of daily living (IADLs, defined as one or more IADL limitation, i.e., a positive survey response to receiving help or supervision using the telephone, paying bills, taking medications, preparing light meals, doing laundry, or going shopping, due to an impairment or health problem) who have Medicaid, Medicare, or private insurance.

This economic evaluation among 6,309,998 eligible US adults found that national implementation of MTMs for patients with diet-sensitive conditions and IADLs could potentially be associated with 1.6 million averted hospitalizations and net cost savings of $13.6 billion annually and $185.1 billion over ten years, from an insurer perspective. The intervention modelled consisted of ten nutritionally tailored MTMs per week for a mean of eight months in each year of intervention.[5]

Case Study by Population: Dual Eligibles in Massachusetts

Community Servings, a medically tailored home-delivered meals (MTM) program based in Boston, has provided MTMs to individuals dually eligible for Medicaid and Medicare through a partnership with Commonwealth Care Alliance (CCA), a Managed Care Organization, since 2015. In a study published in Health Affairs in 2018, Community Servings, Commonwealth Care Alliance, and an external research partner sought to determine whether home delivery of either MTMs or nontailored meals (NTMs) reduces the use of certain health care services and medical spending in the dually eligible individuals receiving these meals. Compared with matched nonparticipants, both MTM and NTM participants had fewer emergency department visits. Participants in the MTM program also had fewer inpatient admissions and lower medical spending. Participation in the NTM program was not associated with fewer inpatient admissions but was associated with lower medical spending. The medical spending was significantly lower for the MTM recipients than for the NTM recipients.[6]

CCA, a not-for-profit community-based Managed Care Organization, administers care for individuals over the age of 21 who are dually eligible for Medicaid and Medicare. CCA offers two plans: One Care, serving Medicaid-eligible individuals between the ages of 21 and 64 who typically qualify for Medicare due to adjudicated disability, and Senior Care Options, serving Medicaid-eligible individuals

[5] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797397

[6] Berkowitz SA, Terranova J, Hill C, Ajay T, Linsky T, Tishler LW, et al. Meal Delivery Programs Reduce the Use of Costly Health Care in Dually Eligible Medicare And Medicaid Beneficiaries. Health Aff. 2018;37(4):535-542.

over the age of 65. Over 70% of the CCA clients receiving Community Servings' MTMs are enrolled in One Care, which targets individuals with high levels of medical and social needs.[7] Roughly 80 percent of CCA's One Care members have multiple chronic health conditions, behavioral health issues, or limitations because of physical and developmental disabilities, including muscular dystrophy or cerebral palsy.[8] The level and complexity of need is illustrated by "Sarah," a One Care client experiencing morbid obesity, pituitary dysfunction, Type 2 diabetes, high blood pressure, chronic kidney disease, blindness, and a history of blood clots. Based on an in-depth nutrition assessment by Community Servings' Registered Dietitian Nutritionists, Sarah receives meals that are low in potassium, low in Vitamin K, non-dairy, and diabetic friendly. Receipt of the meals resulted in significantly less usage of acute care health services and better management of Sarah's complex medical needs.

II. Implementation Challenges and Opportunities

Thanks to the ongoing efforts of CMS, states, and individual health plans, we are seeing progress towards establishing opportunities to support MTMs in programs such as Medicaid and Medicare. These include: Medicaid Section 1115 Demonstration Waivers, Medicaid Managed Care "in lieu of services," Medicare Advantage supplemental benefits/special supplemental benefits for the chronically ill (SSBCI), and the CMS Innovation Center's Value-Based Insurance Design model. And we know that these opportunities will expand further with the implementation of Advance Investment Payments (AIPs) for certain accountable care organizations in the Medicare Shared Savings Program in 2024. Each of these pathways provides a potential opportunity to expand access to these critical services, improve health outcomes, and decrease health care costs. However, in each case, policymakers and plans should be aware of—and responsive to—ongoing challenges to implementation that can limit their reach, impact, and research value.

1115 Waiver Implementation Feedback

To boost chances of success, any pilot design must be reflective of the clinical and practical realities of MTM service delivery and utilization operations on the ground. Large scale pilots in Medicare can look to Medicaid section 1115 demonstrations testing coverage of nutrition interventions for early implementation lessons. On April 24, 2023, FIMC and the Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University, with our partners at the Center for Health Law and Policy Innovation of Harvard Law School and the National Produce Prescription Collaborative, sent a letter to CMS with feedback and recommendations regarding section 1115 demonstrations piloting nutrition interventions, informed by a survey of on-the-ground implementers, participants, and evaluators of these demonstrations. **This letter is an excellent summary of implementation barriers and challenges and is attached as Appendix B. The letter details:**

1. Legal and Regulatory Barriers
2. Practical Barriers
3. Infrastructure Funding and Support

Lack of Predictability

Piecemeal and unpredictable funding significantly impair the scaling of FIM interventions. Additionally, unclear regulations and rules and inconsistent or varying eligibility criteria make it difficult for health plans and service providers to offer the MTM intervention for a significant number of beneficiaries or to sustain programs long-term; all of which ultimately effects our ability to evaluate these partnerships effectively.

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[7] Klein S, Hostetter M, McCarthy D. The One Care Program at Commonwealth Care Alliance. Case Study by The Commonwealth Fund, available at https://www.commonwealthfund.org/publications/case-study/2016/dec/one-care-program-commonwealth-care-alliance

[8] Id.

Granular Implementation of Specific Partnerships

In terms of specific recommendations on the implementation of explicit innovation projects, FIMC agencies have deep expertise in designing screening, referral, service, claims and other billing in the differing partnerships and payment arrangements listed at the top of this section. Given the unpredictable nature of these partnerships, the design is highly context dependent. We are happy to advise further if developing best practices for each of these funding streams is of interest.

Nutrition Quality

Like prescription medications, which are only effective if they are taken, MTMs are only effective if they are consumed, making nutritional quality – and taste - especially important. The composition and quality of the MTM intervention is described in the Food Is Medicine Coalition (FIMC) MTM Nutrition Standards. The Nutrition Standards are maintained and updated according to evidence-based standards and current nutrition science by the FIMC Clinical Committee, which is comprised of Registered Dietitian Nutritionists (RDNs) from FIMC Agencies. The Committee is instrumental in providing input regarding the definitions and applications of medically tailored meals, medically tailored groceries, medical nutrition therapy, and industry-standard nutrition practices. You can find the most up to date MTM Nutrition Standards on the FIMC website.[9]

Strong Public Interest and Support for Food is Medicine Interventions in Healthcare

A recent national survey led by Tufts faculty asked about understanding and perception of FIM interventions among nearly 4,000 U.S. adults across a diverse range of ages, races, ethnicities, income and education levels, and US geographic regions. The results demonstrated strong interest in Food is Medicine interventions in healthcare. Key findings included:

- 80% of respondents somewhat or strongly agreed that they would be more likely to change what they ate if they knew it would reduce the need for prescription medications.
- 70% of respondents somewhat or strongly agreed that the healthcare system should help pay for delivery of healthy groceries or meals to homes of patients with appropriate medical conditions.
- 70% somewhat or strongly agreed that Medicare and Medicaid should help pay for Food is Medicine programs.
- And 70% somewhat or strongly agreed that they would be more likely to recommend their health care insurance program to a friend or colleague if it paid for Food is Medicine programs.[10]

III. Measurement and Evaluation

There is already a robust research base regarding the efficacy of medically tailored meals. Our providers and advocates often hear that this existing research is not enough. For many years, we have advocated for a multi-state, multi-site demonstration within the Centers for Medicare and Medicaid Services (CMS) and/or the Center for Medicare and Medicaid Innovation (CMMI) — which could be designed and implemented using several existing pilot authorities—to robustly test the effects of MTM. This call for demonstration projects has support in Congress – as evidenced by bills put forth in both the 116th and 117th Congresses[11], the Administration – as it was a key part of Pillar 2 of the National Strategy of Hunger, Nutrition and Health,[12] and the community, as it was included in a 2022 report from an independent, bipartisan, multisector stakeholder Task Force[13].

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[9] https://www.fimcoalition.org/our-model
[10] Data unpublished, but in preparation
[11] H.R. 6774 of the 116th Congress: https://www.congress.gov/bill/116th-congress/house-bill/6774
H.R. 5370 of the 117th Congress: https://www.congress.gov/bill/117th-congress/house-bill/5370
[12] https://www.whitehouse.gov/wp-content/uploads/2022/09/White-House-National-Strategy-on-Hunger-Nutrition-and-Health-FINAL.pdf
[13] https://informingwhc.org/2022-task-force-report/

The Center for Medicare and Medicaid Innovation (CMMI) could authorize and fund demonstration projects of medically tailored meals (MTMs) in Medicare, Medicaid, and/or the Children's Health Insurance Program (CHIP) for enrollees with severe or chronic illnesses. MTMs, medically tailored groceries, and produce prescriptions could be tested together as part of a single demonstration project, but the evaluation should assess outcomes separately for each intervention, in addition to combined effects. The Secretary of HHS has the existing authority to scale these models across Medicare, Medicaid, and CHIP, if the demonstration project provides evidence that the expansion would result in cost savings or be cost neutral while maintaining or improving quality of care.

Research Process and Metrics: The Food Is Medicine Action Plan

A similar broad-based group of multisector stakeholders convened to create the Aspen Institute's Food Is Medicine Research Action Plan.[14] The plan ends with 26 recommendations on both how to conduct future FIM research and what the next set of research questions could be. We stand by these recommendations and offer them as an answer to this question. These include recommendations on:

- Conducting FIM research with an equity lens and in partnership with the recipients of service and the community,
- Research design with appropriate powering, combinations of qualitative and quantitative approaches, and process and engagement metrics,
- Opportunities to investigate the intensity and duration of the intervention, and
- Demonstrations testing with or without scaling to household size.

On this last point, it is important to note that nonprofit MTM programs typically provide services at the household level through philanthropic means, thereby supporting the caregiving structure for the client, but also for healthcare. This household level provision is generally not permitted for reimbursement under waivers or health insurance programs (other than, in very limited circumstances, such as in Massachusetts[15]). In our experience, meals provided to individuals living in households are shared with others in the household, and thus lose the intended "dose" effect. For this reason, we should test MTM impact on the individual vs. household level.

Key Outcomes Measures

Key utilization outcome measures that have already been demonstrated but should be expanded upon are hospital, emergency room, and nursing home admissions; net healthcare costs; and medication adherence.

Key patient-centered outcome measures should include food security, nutrition security, malnutrition, self-reported physical and mental health, change in activities of daily living, beneficiary satisfaction, and quality of life.

Disease-Specific Outcomes

MTM service providers have also generated evidence-based recommendations for evaluative outcomes for severe, chronic, and diet-related diseases and conditions. The following clinical outcome recommendations are based off MTM research conducted in partnership with community-based organizations nationwide. They should be expanded for other disease states.

- **Diabetes: Reduction in HbA1c.** Existing evidence demonstrates that the MTM intervention is associated with 0.3-1.8% reduction in HbA1C. [16]

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[14] https://www.aspeninstitute.org/wp-content/uploads/2022/01/Food-is-Medicine-Action-Plan-Final_012722.pdf
[15] https://www.hhs.gov/about/news/2022/09/28/hhs-approves-groundbreaking-medicaid-initiatives-in-massachusetts-and-oregon.html
[16] Project Open Hand in San Francisco found that enrollees receiving the medically tailored meal intervention for six months experienced an average of 0.48% reduction in A1C levels: Kartika Palar et al, Comprehensive and Medically Appropriate Food Support Is Associated with Improved HIV and Diabetes Health, JOURNAL of URBAN HEALTH, (2017). https://pubmed.ncbi.nlm.nih.gov/28097614/

- **Hypertension: Reduction in systolic and diastolic blood pressure.** Existing evidence demonstrates that nutrition interventions can be associated with 3.2-9 mm HG reduction in systolic blood pressure and 2.5-5.3mm Hg reduction in diastolic blood pressure.[17]
- **Hyperlipidemia: Reduction in LDL cholesterol, increase in HDL cholesterol and triglyceride reduction.** Existing evidence demonstrates that nutrition interventions can be associated with a 8-28mg/dL total cholesterol reduction, 8-22mg/dL LDL cholesterol reduction, 2.4-6mg/dL HDL cholesterol increase, and 15 to 153mg/dL triglyceride reduction.[18]
- **Mental and Behavioral Health: Reduction in scores on outcomes measures** like the PHQ2 and PHQ9, medication adherence, and/or reduction in other symptoms.[19]
- **HIV/AIDS: Reduction in detectable viral load, medication adherence and other markers.**

Opportunities exist to define more and better outcome measures for specific disease states such as heart failure, different cancers, kidney disease, neurodegenerative diseases, and more. FIMC is in the process of writing a response to the recently released Request for Information (RFI): Food is Medicine Research Opportunities from NIH, which is due June 30.[20] We respectfully request the opportunity to resubmit an updated version of this section post the submission of that RFI.

Additional Available Nutrition Data: RDNs and the Nutrition Care Process

Identifying the presence of certain nutrition diagnoses and the impact of the RDN interventions using the Nutrition Care Process should also be measured. In the course of service, MTM recipients interact with an RDN regularly for their nutrition care. There is a wealth of qualitative and quantitative data within these experiences, according to the requirements of the Nutrition Care Process, that could be leveraged to add depth and breadth to any analysis of MTM. Nutrition assessment data is categorized into the following domains:

- **Food/Nutrition-Related History** contains terms that capture data typically collected from an interview with the client where food and nutrition intake and related behaviors are discussed.
- **Anthropometric Measurements** includes terminology that helps describe the physical measurements for the client such as height, weight, body mass index, growth pattern indices/percentile ranks and weight history.
- **Biochemical Data, Medical Tests, and Procedures** includes terms for laboratory data and medical tests.
- **Nutrition-Focused Physical Findings** includes terminology that describes nutrition-related physical signs or symptoms derived from a nutrition-focused physical exam, interview, or health record. Examples include subcutaneous fat, muscle, oral health, suck/swallow/breathe ability, and appetite.
- **Client History** includes terminology that captures the client's personal history such as age, gender, ethnicity, and reported medical and social history.

Additionally, a systematic review of medically tailored nutrition effectiveness for diabetes suggested that enrollees receiving medically tailored nutrition for six months experienced anywhere from 0.3-1.8% reduction in A1C: Franz MJ, et al. Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process. J Acad Nutr Diet. 2017 Oct;117(10):1659-1679. doi: 10.1016/j.jand.2017.03.022. Epub 2017 May 19. PMID: 28533169. https://pubmed.ncbi.nlm.nih.gov/28533169/

Finally, a systematic review and meta-analysis of healthy food prescription programs ranging from one to six months in duration saw an average of 0.8% reduction in A1C: Bhat S, et al. Healthy Food Prescription Programs and their Impact on Dietary Behavior and Cardiometabolic Risk Factors: A Systematic Review and Meta-Analysis. Adv Nutr. 2021 Oct 1;12(5):1944-1956. doi: 10.1093/advances/nmab039. PMID: 33999108; PMCID: PMC8483962. https://pubmed.ncbi.nlm.nih.gov/33999108/

[17] Franz MJ, et al. 2017
[18] Ibid.
[19] Finally, clinical outcome recommendations for individuals with depression are based on data collected from implementation of a 6-month medically tailored meal intervention conducted in San Francisco by Project Open Hand. The measures of depression are based on enrollee PHQ-2 and PHQ-9 results. The outcome, and subsequent recommendation for measurement in forthcoming pilots, was a 1.74 point reduction in PHQ-9 enrollee scores.
[20] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-107.html

- **Assessment, Monitoring, and Evaluation Tools** capture tool ratings that assess health or disease status or risk.
- **Etiology Category** communicates the type of nutrition diagnosis etiology
- **Progress Evaluation** measures progress towards a nutrition related goal(s) and resolution of a nutrition diagnosis(es)

Existing Opportunity for Evaluation: Medicare Part C: Utilization/Outcomes Data
The increasing provision of MTM in Medicare Part C provides a powerful existing opportunity to evaluate efficacy with only a small administrative request. CMS should make data publicly available on the utilization of Medicare Part C coverage of Food is Medicine programs under the Special Supplemental Benefits for the Chronically Ill. Utilization data should include the amount spent on Food is Medicine treatments, the type of treatments, the geographic reach, and the quantity of patients served. FIMC urges CMS to require Medicare Advantage plans to report on the nutritional standards of meals provided via SSBCI as well. These data could facilitate research on payors' experiences in implementation, identification of barriers to expansion of these benefits, and patient experience.

IV. Opportunities to Pilot and Evaluate MTMs through Existing CMS and CMS Innovation Center Models

Given the critical role that MTMs play in the overall treatment plans of clients using the intervention, we believe that MTMs should not be seen as simply an optional add-on to standard medical care. MTMs should be recognized for what they fundamentally are—a medically necessary component of treatment and management for complex illness. Accordingly, MTMs should be incorporated more broadly and equitably into programs such as Medicaid and Medicare as a standard covered benefit with coverage determination that aligns with the intensity and duration needed to achieve improvement and/or stabilization in health.

If CMS is not yet prepared or able to take this important step forward, we encourage CMS to consider what steps it could take to use existing models to expand the impact of MTM and thereby address any gaps that CMS currently sees in the evidence base. Specifically, we recommend that CMS consider strategies such as:

1. Creating the Next Generation of the Accountable Health Communities Model ("AHC 2.0")

The CMS Innovation Center's Accountable Health Communities (AHC) model took an important step forward in evaluating the impact of expanding screening, referral, and navigation services for health-related social needs (HRSNs) for Medicaid and Medicare enrollees.[21] Initial evaluations found that patients were highly interested in receiving navigation services for HRSNs, but that resolution of HRSNs based on navigation alone was low.[22] Notably, while this model provided funding for screening, referral and navigation, it did not provide funding for HRSN services themselves. This raises the question of whether lack of support for responsive services contributed to limited impact in resolving patient needs. The Innovation Center could assess this question and create an important opportunity to pilot and evaluate individual services like MTMs, by establishing a second-generation Accountable Health Communities model (AHC 2.0) to address this critical gap. Such a model could place an emphasis on not only screening for HRSNs, but assessing the patient needs for certain specific services (including MTM), connecting patients to those services, funding them, and evaluating impact. Such a model would create an opportunity to evaluate MTMs across multiple states, settings, and insurance types (both Medicaid and Medicare) providing a much-needed national pilot of the intervention.

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[21] https://innovation.cms.gov/innovation-models/ahcm
[22] https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt-fg

2. Accountable Care Organizations (ACO) Model(s)

As an ongoing model with multiple evolutions, Medicare Accountable Care Organizations (ACOs) with aligned financial incentives serve as an ideal test case for medically tailored meals. Because ACOs are accountable for cost and outcomes and are not bound by the constraints of Medicare fee for service, there is both the incentive and the payment mechanism to enable the delivery of the MTM intervention. Additionally, ACOs ensure that patients to get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. The MTM intervention could be embedded into any number of discrete models for populations to test efficacy in a diversity of situations.[23]

3. Disease-specific CMS Innovation Models

Given the appropriateness of MTMs for complex illnesses, we suggest here a few of the variety of disease-specific innovation models offered at CMS as appropriate test arenas. The following list is by no means exhaustive, and expansions are welcome.

- Kidney Care Choices - Kidney Care Choices (KCC)[24] offers strong financial incentives for health care providers to manage the care for Medicare beneficiaries with chronic kidney disease (CKD) stages 4 and 5 and ESRD, to delay the onset of dialysis and to incentivize kidney transplantation. The model provides an exceptional opportunity for CMS to understand whether MTM interventions offer benefits for model participants receiving MTMs compared with model participants who do not. Clients with chronic kidney disease are a growing population of MTM recipients across the country and several partnerships already exist in philanthropy to provide MTMs to dialysis patients.
- Enhancing Oncology Model – Regrettably CMMI's Oncology Care Model (OCM) did not integrate nutrition as a component of care into its first 6-month outpatient chemotherapy care.[25] The Enhancing Oncology Model (EOM), which will commence later in July of 2023, aims to test how to improve health care providers' ability to deliver care centered around patients, consider patients' unique needs, and deliver cancer care in a way that will generate the best possible patient outcomes. The patient-centered focus of this model, as well as our previous explanation of how MTMs support people in cancer care and how this initiative bolsters the Administration's Cancer Moonshot initiative to improve the experience of people and their families living with and surviving cancer, makes the EOC model another ideal testing arena.

  CMS could adjust the per-patient-per-month payments for participating practices that wish to offer MTM interventions as a component of patient management for ECM beneficiaries. Additionally, the ECM alternative payment model could facilitate access to care with a Registered Dietitian Nutritionist via the MTM intervention that would otherwise not be available in Medicare Fee-for-Service. Due to poor staffing ratios and no benefit for medical nutrition therapy (MNT) for oncology diagnoses under Medicare Part B, most Medicare beneficiaries do not have access to nutrition care by qualified providers in outpatient cancer centers.[26] FIMC is available to inform the estimation of the total cost of care of providing of MTM interventions to ECM populations.

4. Building an MTM Pilot Through Incentives to Adopt MTM in Existing Models

As noted above, some Innovation Center models and CMS programs already provide (or will soon provide) the flexibility to support access to MTMs. These include, for example, the Value-Based

[23] https://innovation.cms.gov/innovation-models/aco
[24] https://innovation.cms.gov/innovation-models/kidney-care-choices-kcc-model
[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8550270/
[26] https://www.hindawi.com/journals/jo/2019/7462940/

Insurance Design Model (VBID), in which Medicare Advantage plans are given additional flexibility in providing supplemental benefits, and the Medicare Shared Savings Program (MSSP), in which some ACOs will start receiving Advance Investment Payments in 2024 that can be used to provide MTM (among other options). If uptake by plans and ACOs in such models is high enough, CMS and the Innovation Center could use data from these models to evaluate impact of MTM. To encourage such uptake, CMS would need to consider what levers it has available to incentivize plan and ACO participation (e.g., additional financial incentives related to provision of MTM and/or technical assistance supports). Additionally, CMS would want to consider whether additional guidance or requirements would be necessary to ensure that MTM models adopted by such plans and ACOs are consistent enough for meaningful evaluation.

Additionally, alternative payment models (APM) used in various CMMI models are an important vehicle to enabling the inclusion of MTM intervention in multiple models. Any payment methodologies intended to allocate payments for the provision of MTM interventions as part of a model must factor in the actual cost of delivering the intervention, which is more than a meal. The existing publicly available information about cost lacks context and may not factor in the total cost of the intervention, independent of geographic variation. FIMC is available to help inform the development of APM methodology using a combination of inputs that may include existing HCPCS, related CPT codes, current partnerships, and other information. CMMI has updated models in the past and could update existing models to accommodate the inclusion of MTMs.

5. Gathering Data Proactively from Medicare Advantage Plans:

Finally, as noted above, Medicare Advantage plans can also already provide MTM as general supplemental benefits or special supplemental benefits for the chronically ill (SSBCI). As a result, CMS could seek to gather additional data from plans using these options in order to evaluate impact. If CMS were to pursue this option, it would be important to distinguish and exclude plans that are providing standard meals as opposed to medically tailored meals from the analysis.

Conclusion

We appreciate CMS's recognition of the importance of Food is Medicine and your attention to addressing the need for Medically Tailored Meals in Medicaid, CHIP, and Medicare. We hope we have answered some of your more critical questions regarding population targeting and duration of the MTM intervention, implementation and measurement, and evaluation. Further, we believe that there are existing models where MTMs could be seamlessly incorporated into care for vulnerable populations. If we have not answered your questions sufficiently, please let us know and we can continue the conversation.

Thank you for your consideration of our perspective and recommendations regarding this important framework as you plan future innovations at CMS.

Sincerely,

Food is Medicine Coalition

The Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University

The Food is Medicine Coalition (FIMC) is a national coalition of nonprofit organizations that provide medically tailored meals (MTMs) and groceries, medical nutrition therapy and nutrition counseling and education to people in communities across the country living with severe and chronic illnesses. We gather together to advance equitable access to these life-saving interventions through policy change, research and evaluation, and best practices. FIMC agencies created the medically tailored meal model and maintain the nutrition standards for the intervention. We offer a diverse community of learning for existing practitioners and equip new organizations to launch medically tailored meal programs.

The Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University is a leading U.S. institution focused on education, research, and public impact around the food system, from soil to society. The School's five divisions and additional centers and institutes are renowned for the application of scientific evidence to national and international policy. Tufts University, located on campuses in Boston, Medford/Somerville, and Grafton, Massachusetts, and in Talloires, France, is recognized among the premier teaching and research universities in the U.S. Learn more at nutrition.tufts.edu/ and tuftsfoodismedicine.org.

Appendices that follow:

Appendix 1: Letter: Addressing Health-Related Social Needs in Section 1115 Demonstrations

Appendix 2: Letter: Food is Medicine Section 1115 Demonstrations Implementation Survey and Recommendations

April 26, 2023

Daniel Tsai
Deputy Administrator and Director
Center for Medicaid and CHIP Services
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Addressing Health-Related Social Needs in Section 1115 Demonstrations

Dear Deputy Administrator Tsai:

On behalf of the Food is Medicine Coalition (FIMC), we write to provide recommendations regarding the framework offered in CMS's December 2022 webinar presentation: Addressing Health-Related Social Needs in Section 1115 Demonstrations.[1] FIMC appreciates CMS's ongoing work and dedication to supporting states and other stakeholders in addressing the social determinants of health and health-related social needs in Medicaid, CHIP, and Medicare.

The Food is Medicine Coalition (FIMC) is a national coalition of nonprofit organizations focused on advancing policy, research, and best practices around evidence-informed medical food and nutrition interventions. Our partner agencies provide medically tailored meals (MTMs) and groceries, as well as medical nutrition therapy and nutrition counseling and education to people in communities across the country who are living with serious and chronic illnesses.

An outsized portion of adverse health outcomes and healthcare costs find their root in lack of access to good nutrition,[2] which is predicated on healthcare inequities – both racial and socioeconomic.[3] FIMC seeks to address the inequity that already exists and to rebalance health in favor of our clients through the services we provide. Peer-reviewed research shows that access to MTMs leads to impressive improvement in health outcomes and reductions in healthcare costs.[4] A recent study modelled the efficacy of implementing the MTM framework nationwide and found extraordinary results: if all eligible patients received access to MTMs, in just the first year of service, approximately 1.6 million hospitalizations could be avoided for a net cost savings of $13.6 billion. Even in modelling subgroups, savings were robust: individuals living with food insecurity, diabetes, or cardiovascular disease evidenced savings on top of the aggregate.[5] Because of compelling research and pilot results, some individual states and Medicaid and Medicare managed care plans have begun to use waivers and regulatory flexibilities to test coverage of MTMs.[6] While much success has been seen in these pilots, they remain on the margins of innovation and fall short of establishing the widespread coverage needed to ensure equitable access to these critical services across the U.S.

Thus, **we appreciate CMS's efforts to assist states with addressing health-related social needs (HRSN) in Medicaid and CHIP, including CMS's December 2022 webinar detailing its framework for evaluating state proposals under Section 1115 authority to cover evidence-based services that address HRSN, such as medically tailored meals**. Nutrition interventions considered for coverage under the framework, including MTMs and produce prescriptions, build upon and reach beyond population-level food security programs (like SNAP) and allow clinicians to address the upstream health care causes of diet-related chronic conditions. The December webinar framework is a significant step forward in assisting Medicaid programs across the country seeking to leverage Food is Medicine to improve health outcomes and health equity in their states.

To maximize and adequately test these healthcare interventions, we recommend that CMS clarify its Section 1115 Demonstration framework regarding medically tailored meals and other nutrition supports to permit reauthorization of these services beyond six months as medically necessary.

Distinguished from federally funded meal programs with a primary focus on addressing hunger, MTMs are a healthcare intervention for the people who consume them. MTM patients living with severe illnesses are referred by medical professionals or healthcare plans and receive deliveries of medically tailored meals made from healthy ingredients to their homes. Meal plans are tailored to the medical needs of recipients living with chronic diseases by a Registered Dietitian Nutritionist (RDN) according to the FIMC MTM Nutrition Standards[7] and are combined with medical nutrition therapy and/or nutrition counseling to reduce hospital visits. MTMs may be indicated for many conditions including, but not limited to diabetes, heart failure, HIV/AIDS, chronic kidney disease, cancers, End Stage Renal Disease (ESRD), behavioral health conditions and pregnancy. The plurality of our clients live with multiple, co-morbid conditions. Most experience activities of daily living limitations and are unable to shop or cook for themselves because of their complicated medical situations.

A robust and growing body of evidence shows that inclusion of medically tailored meals as part of a patient's treatment plan improves hemoglobin A1C levels in patients with diabetes, body mass index (BMI) scores, blood pressure, and overall dietary quality; results in higher patient satisfaction; and reduces hospitalizations, emergency room utilization, and health care costs.[8] **However, limiting enrollment in MTM services to 6 months, as suggested in CMS's December webinar, may diminish these benefits for patients and programs, and therefore hinder states' and CMS's ability to evaluate the efficacy of these interventions.**

For example, the published research suggests MTM enrollment for longer than six months may be necessary to improve health outcomes and result in reductions in healthcare utilization. A recent study found that the average time individuals received medically tailored meals in previous studies with documented positive impacts on healthcare utilization was 8 months, with some individuals receiving meals for 12-24 months.[9] Additionally, as noted above, MTMs can be prescribed for pregnancy-related conditions. Treatment for these conditions could be diminished if the intervention cannot be provided for the duration of the pregnancy or longer (at least 9 months). Similarly, Community Care Cooperative, a Medicaid Accountable Care Organization in Massachusetts, recently shared preliminary data for its medically tailored meals program, which allows physicians to reassess their patients every 3 months and extend the meal services for 3 months at a time based on the clinical evaluation. Community Care Cooperative found significant improvements in HbA1c among members with diabetes within a cohort in which most members had received 6-12 months of meals

per provider-recommended reauthorization. Reauthorization based on clinician assessment of patient conditions and ongoing medical needs is also consistent with person-centered and Medicaid standards of care. Medicaid 1115 Demonstrations addressing health-related social needs and covering services such as MTMs should apply similar clinical standards. Many FIMC agencies already reassess clinical need for continuation of services at 6-month intervals.

Reauthorization for services when medically necessary is a common-sense approach that can maximize the benefits of MTM services for patients and states, allow CMS and states to properly assess the impacts of these interventions, and mirrors clinical standards and patient-centered decision making for other Medicaid services.

FIMC appreciates CMS's recognition of the importance of Food is Medicine and your commitment to addressing health-related social needs in Medicaid, CHIP, and Medicare. Thank you for your consideration of our perspective and recommendations regarding this important framework.

Sincerely,

Alissa Wassung
Executive Director
Food Is Medicine Coalition

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[1] Centers for Medicare & Medicaid Services, Addressing Health-Related Social Needs in Section 1115 Demonstrations (Dec. 6, 2022), https://www.medicaid.gov/medicaid/downloads/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf.
[2] Hugh Waters & Marlon Graf, Milken Inst., Costs of Chronic Disease in the U.S. (2018), https://milkeninstitute.org/sites/default/files/reports-pdf/ChronicDiseases-HighRes-FINAL.pdf; Christian A. Gregory & Alisha Coleman-Jensen, U.S. Dep't of Agric., Food Insecurity, Chronic Disease, and Health Among Working-age Adults (2017), https://www.ers.usda.gov/webdocs/publications/84467/err-235_summary.pdf?v=2983.5.
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[4] See, e.g., Seth A. Berkowitz et al. Association Between Receipt of Medically Tailored Meal Program and Health Care Use, 179 JAMA Internal Med. 786 (2019), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2730768 (doi:10.1001/jamainternmed.2019.0198); Seth A. Berkowitz et al., Meal Delivery Programs Reduce the Use of Costly Health Care in Dually Eligible Medicare and Medicaid Beneficiaries, 37 Health Affairs 535 (2018), https://doi.org/10.1377/hlthaff.2017.0999.

[5] Kurt Hager et al., Association of National Expansion of Insurance Coverage of Medically Tailored Meals with Estimated Hospitalizations and Health Care Expenditures in the US, 5 JAMA Network Open e2236898 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797397 (doi:10.1001/jamanetworkopen.2022.36898).

[6] https://www.fimcoalition.org/healthcare-innovation

[7] https://www.fimcoalition.org/our-model

[8] See Sarah Downer et al., Center for Health Law and Policy Innovation and Aspen Institute, Food is Medicine Research Action Plan 60-63 (2022), https://www.aspeninstitute.org/wp-content/uploads/2022/01/Food-is-Medicine-Action-Plan-Final_012722.pdf.

[9] Kurt Hager et al., Association of National Expansion of Insurance Coverage of Medically Tailored Meals with Estimated Hospitalizations and Health Care Expenditures in the US, 5 JAMA Network Open e2236898 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797397 (doi:10.1001/jamanetworkopen.2022.36898).

April 24, 2023

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Food is Medicine Section 1115 Demonstrations – Implementation Survey and Recommendations

Dear Administrator Brooks-LaSure:

We write as participants in the 2022 White House Conference on Hunger, Nutrition, and Health and longtime experts in research, law, and implementation of Medicaid and other health care food and nutrition policies to share feedback and recommendations regarding section 1115 demonstrations piloting nutrition interventions, informed by a survey of on-the-ground implementers, participants, and evaluators of these demonstrations.

The White House Conference highlighted the capacity of "Food is Medicine" interventions – such as medically tailored meals, medically tailored groceries, and produce prescriptions – to help prevent and manage costly chronic health conditions, improve household food security, and address health disparities. Critically, the accompanying National Strategy included commitments from CMS to assist states in using section 1115 demonstrations to test the expansion of Medicaid coverage for these interventions, including through the issuance of guidance. In December 2022, we wrote with recommendations urging CMS to issue this guidance and to encourage states to submit Medicaid section 1115 waivers to widely and equitably pilot and evaluate the impacts of Food is Medicine interventions. We applaud CMS for its commitments in the National Strategy and its efforts thus far to address them, including its December 2022 webinar detailing a framework for evaluating state section 1115 proposals to cover evidence-based services that address health-related social needs (HRSN), such as medically tailored meals and produce prescriptions.

At this critical time in which individuals and families have lost SNAP emergency assistance and are undergoing post-PHE Medicaid changes, we continue to ask CMS to support states and stakeholders seeking to address nutrition insecurity, chronic illness, and health care costs through Food is Medicine by issuing guidance and providing technical assistance regarding 1115 demonstrations. Importantly, **this guidance should reflect and be responsive to the clinical and practical realities of implementation, which can limit service access, impact, and research value.** To that end, **this letter provides learnings and recommendations informed by a survey** of individuals and organizations with real-world implementation and delivery experience, patients with lived experience, and researchers in states with current Medicaid 1115 demonstrations or proposals and in states where barriers are preventing successful proposal of demonstrations.

Survey Background

The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI), Food is Medicine Coalition (FIMC), and National Produce Prescription Collaborative (NPPC) developed the survey, which was distributed by FIMC and NPPC to their members – including FIM provider organizations and other stakeholders – during March 2023.

Thirty-five respondents included Food is Medicine (FIM) program participants, providers, researchers, advocates, and government officials from 19 states, as well as representatives from national nonprofit organizations and trade associations. Respondents represent states at various stages of section 1115 demonstrations that address nutrition insecurity. Specifically, respondents include representatives from:

- 5 states with current 1115 waivers covering FIM services (AR, CA, MA, NC, OR)
- 2 states with pending 1115 waiver proposals that would cover FIM services (NM, NY)
- 5 states with legislative proposals directing the state's Medicaid agency to submit 1115 proposals that would cover FIM services (CT, FL, IL, PA, TX)
- 7 other states (CO, DC, GA, MD, MI, MN, OH)

Of FIM provider respondents, over one-third currently provide services through an 1115 waiver. Of provider respondents who are not currently providing FIM services through an 1115 waiver and who answered the question, 100% are interested in doing so. Respondents also provide services through a variety of other health care funding mechanisms, including section 1915(b), (c), and (k) waivers; dual demonstrations; in lieu of services; value-based payment arrangements; and various other contracts with managed care.

Survey Results and Recommendations

To increase equitable patient access to services, return on investment, and overall chances of pilot success, section 1115 demonstrations targeting nutrition insecurity must be reflective of clinical and practical experiences of service delivery and utilization. Moreover, lessons of stakeholders in early-implementation states are applicable beyond the 1115 demonstration and Medicaid contexts: practical, large-scale pilot learnings should be applied to any future CMS programs in this area.

Findings from the survey include implementation challenges and opportunities in the areas of (1) legal/regulatory barriers, (2) infrastructure/practical barriers, and (3) infrastructure funding and support. Overall, respondents desired more "guidance" and "regulation" from CMS and state Medicaid agencies that would create "consistency," "cohesion," "simplicity," "efficiency," and "streamlined systems" but emphasized that the design of the waiver needs to meet the reality on the ground. As coined by one respondent, "baked-in inefficiencies" can prevent demonstrations from meeting Medicaid enrollees' needs.

1. Legal and Regulatory Barriers

a. *Service Payment and Reimbursement Rates*

Survey respondents identified "service payment and reimbursement rates" as the top regulatory barrier to successful provision of nutrition intervention services in 1115 demonstrations. One FIM provider

reported that their reimbursement rate is almost $4 lower than through Medicare. According to some providers, rates do not cover the administrative costs required for these new programs. In California, respondents report that the state's rate guidance for medically tailored meals (MTMs) was developed without the consultation of California MTM providers and instead relied on North Carolina's fee schedule and other sources. This process led to rates which failed to reflect the relevant treatment and cost of living in California. Similarly, New York's demonstration proposal refers to North Carolina's fee schedule as a model for HRSN services reimbursement (although the process for determining the rates in New York is not clear from the proposal).[1] Respondents also highlighted equity issues due to low reimbursement rates. In particular, the rates do not cover attempts to provide services in additional and/or rural geographies where providers are looking to fill unmet needs.

Recommendation: CMS guidance should encourage "best practices" for fee schedules and reimbursement that promote equity and service access. For example, rate guidance should be developed in consultation with relevant service providers and be reflective of state and local cost of living and costs of providing high-quality services. Additionally, rate guidance can allow for increased rates for rural areas and local providers seeking to address expanded geographies, populations, or other unmet needs. CMS guidance can also help states consider how new administrative costs for payers and providers (that are not covered by reimbursement rates) can be addressed by other funding sources, such as demonstration infrastructure funds.

b. *Data and Privacy Requirements*

"Data and privacy requirements" were the second-leading legal barrier identified. In narrative responses, multiple respondents specifically mentioned HIPAA compliance as a challenge. Many community-based organizations (CBOs) – especially smaller CBOs and CBOs beginning their foray into FIM service provision – struggle to understand and adapt to the requirements of HIPAA and other privacy and data protections. Not only is the law often unclear, investments in legal and other compliance support needed to establish this infrastructure are costly. Additionally, HIPAA-covered entities often refrain from sharing pertinent information with CBOs or impose additional barriers to sharing information (such as requiring a business associate agreement where a business associate relationship does not seem to exist). As a result, meaningful CBO-health care partnerships are regularly stymied. As with the reimbursement rate example above, this can exacerbate health inequity, as barriers are more difficult to overcome in rural communities and/or where local CBOs attempt to fill otherwise unmet needs.

One goal of the section 1115 demonstrations should be to ensure that CBOs can sustain high value services over the long term. Integral to that aim is CBO development of the technical competencies necessary to become health care compliant vendors (such as HIPAA compliance) where required. Of note, respondents in North Carolina have faced barriers to integration posed by the state's HRSN referral platform, NCCARE360 – which has created a system for CBOs outside the scope of HIPAA but equally as burdensome.[2] While the objective of the platform is noble, the result has been duplication of work for providers with contracts outside the waiver, no "on ramp" towards integration into the North Carolina Medicaid program, and limited service access.

Recommendation: CMS can support the Department of Health and Human Services (HHS) in developing specific guidance, tools, and training for community-clinical partnerships navigating HIPAA and other similar requirements. HHS Office for Civil Rights currently offers a range of resources; however, these resources rarely target or address CBOs and social service providers. Essential to

effectively supporting information sharing to coordinate services is an understanding that activities to support HRSN are varied and evolving. Ultimately, partners must understand when obligations arise, when they do not, and how to comply with responsibilities that attach.[3] Clear, targeted guidance, resources, and supports for HIPAA and other compliance issues – focused on eventual integration into health care when needed – can help CBOs and other stakeholders prepare for sustainable, long-term success. Additionally, clear national guidance will reduce repeated use of infrastructure funds to address the same legal questions across multiple different partnerships, increasing efficiency and allowing these funds to be directed elsewhere.

c. *Eligibility Criteria*

Respondents identified service "eligibility criteria" as the top regulatory barrier for participant uptake of FIM services. Several respondents noted that complicated and conflicting eligibility criteria and processes prevent eligible individuals from enrolling in services, threatening to undermine the success of the demonstration. Respondents also noted that eligibility criteria often varied based on geography, creating significant equity concerns.

Additionally, the majority of respondents disfavored a bright-line "6-month duration limit" for service eligibility. Several respondents noted that a 6-month duration may be sufficient for many patient populations, but based on clinical evidence and experience, some diagnoses and/or individual patients may require longer treatment. High-risk pregnancy was frequently cited as an example of a condition indicated for longer treatment. Respondents noted that shorter-than-needed durations can hinder the efficacy of the intervention and the ability to demonstrate health care value. For example, a recent study found that the average time individuals received medically tailored meals in previous studies with documented positive impacts on health care utilization was 8 months, with some individuals receiving meals for 12-24 months.[4]

Recommendation: To supplement CMS's requirement that "all HRSN services must be medically appropriate, as determined using state-defined clinical and social risk criteria,"[5] CMS should require that states implement standards for managed care plans applying these criteria. Our survey pinpoints the plan level as a pain point at which eligibility criteria often become a barrier to care. In California, where plans are allowed to adopt narrower eligibility criteria than the state's criteria, plan coverage criteria vary widely, leading to difficulties for CBO providers delivering services and contributing to lower-than-expected service enrollment.[6] In Los Angeles County, MCOs are undertaking an effort to align various demonstration features, including service eligibility criteria. At least one CBO-MCO partnership expects this will increase low service uptake under the waiver.[7]

Additionally, we recommend that CMS clarify its section 1115 demonstration framework regarding nutrition supports to permit reauthorization of these services beyond 6 months when medically necessary. This recommendation aligns with clinical policy for other Medicaid services and will allow demonstrations to maximize and adequately test FIM health care services.

d. *States without Demonstrations: Budget Neutrality and Financials*

"Budget neutrality and financials" were identified as the top legal and regulatory barriers for successful demonstration proposal in states without 1115 FIM demonstrations. Beyond states' own fiscal challenges, respondents noted that some states that may otherwise be interested in addressing nutrition

insecurity, costly chronic illness, and/or health disparities, are limited or deterred by the complexity of CMS's section 1115 actuarial requirements. These barriers most often hinder progress in states with less waiver experience and fewer resources to dedicate towards innovation.

Recommendation: We appreciate that CMS has made efforts to address various issues with its budget neutrality policy, particularly regarding flexibility for states seeking to pilot HRSN coverage.[8] To further encourage states with less experience and/or bandwidth to utilize 1115 demonstrations, CMS could provide states with additional guidance, examples of budget neutrality calculations, and actuarial support in preparing evaluations.

2. Practical Barriers

a. *Referral Infrastructure and Coordination with Managed Care Plans*

Both "referral infrastructure" and "coordination with managed care plans – including varying contracts and systems among plans" were selected as the top infrastructure or practical barriers to the successful implementation of 1115 demonstrations. When respondents elaborated on these selections, the challenges were often related to each other and to a lack of resources to cover added administrative burden. Overall, respondents find that plan contracts and systems often vary, requiring funding and resources for multiple infrastructure investments. Statewide referral platforms or "hubs" were viewed as a help or hinderance for these issues, depending on design and implementation.

Recommendation: CMS guidance can encourage "best practices" for managed care-CBO contracting and state "hub" proposals that promote continuity and integration. For example, North Carolina has developed and released model contracts between its health plans and network leads and its network leads and CBOs providing HRSN services under its 1115 waiver.[9] CMS should also closely review state "hub" proposals, which should integrate existing government and other systems (e.g., electronic medical record sharing systems, such as the SHIN-NY system in New York, and referral systems through government programs, such as state Departments of Aging), to ensure they mitigate duplication, reduce administrative burden, and eliminate access barriers for enrollees.[10] As described by North Carolina respondents, state referral hubs should not remove CBOs from the health care service delivery system, but rather provide an on-ramp to integration.[11] For example, hubs can play an important role in assisting CBOs with claims and billing (perhaps starting with invoicing), while still building CBO competency to eventually transition to more integrated Medicaid claims submission. This would allow CBO and hub investments to translate directly into sustainable skills and infrastructure for CBOs that can be parlayed into other contracts and partnerships beyond the demonstration.

b. *States without Demonstrations: Coordination with Managed Care Plans and State Medicaid Agency*

Similarly, in states without 1115 demonstrations, respondents identified "coordination with managed care plans" and "coordination with state Medicaid agencies" as the top infrastructure and practical barriers for successful waiver proposal. Best practices resources, which could highlight successful models in early-implementation states, could help stakeholders in these states with coordination. Notably, concerns regarding political/ideological opposition fell below these and other concerns.

3. Infrastructure Funding and Support

We asked survey respondents to indicate how they have or would use demonstration infrastructure funds: 100% of respondents who answered the question selected "workforce development, including paying for staff" and 80% of respondents selected "technology." Beyond funds to build the infrastructure needed to implement programs, respondents indicated needs for "claims and billing training" and "IT systems development."

Recommendation: Infrastructure funding and support is vital to the success of these demonstrations. We appreciate CMS's recent framework highlighting the availability of these funds.[12] CMS can provide additional guidance and example best practices for equitable distribution of infrastructure funding to assist states in the development of their support programs. CMS can also highlight how states have created on-ramps for claims and billing, IT systems development, and other infrastructure progress. For example, in California, Department policy allows CBOs to invoice, rather than requiring integrated claims billing.[13] Several managed care-CBO partnerships have noted that this policy has allowed for successful initial operationalization of the program, with partners moving towards integrated billing once it is more established.[14] Additionally, CMS can collaborate with and support coordinated efforts in the field to establish medical billing and coding infrastructure that accurately describes FIM treatments in clinical care.

The current groundswell of state action on section 1115 demonstrations is proof that stakeholders are eager to address the intersection of hunger, nutrition, and health. We thank CMS for its commitment in these areas and for consideration of our findings and recommendations to inform and strengthen related policies. Please let us know if you would like us to arrange a call to further discuss this letter, answer any questions, or provide additional information.

Sincerely,

Center for Health Law and Policy Innovation of Harvard Law School

Food is Medicine Coalition

The Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University

National Produce Prescription Collaborative

cc: Daniel Tsai
Deputy Administrator and Director, Center for Medicaid & CHIP Services

Hannah Katch
Senior Advisor, Centers for Medicare & Medicaid Services

*The **Center for Health Law and Policy Innovation of Harvard Law School** (CHLPI) advocates for reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic illnesses. We have an active portfolio dedicated to nurturing the integration of Food is Medicine interventions into health care delivery and financing. A central aspect of this work involves analysis of and education on the application of health law and policy frameworks to exciting new innovations that make our health system more equitable, outcome driven, and cost-effective.*

*The **Food is Medicine Coalition** (FIMC) is a national coalition of nonprofit organizations that provide medically tailored meals (MTMs) and groceries, medical nutrition therapy and nutrition counseling and education to people in communities across the country living with severe and chronic illnesses. We gather together to advance equitable access to these life-saving interventions through policy change, research and evaluation, and best practices. FIMC agencies created the medically tailored meal model and maintain the nutrition standards for the intervention. We offer a diverse community of learning for existing practitioners and equip new organizations to launch medically tailored meal programs.*

***The Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy at Tufts University** is a leading U.S. institution focused on education, research, and public impact around the food system, from soil to society. The School's five divisions and additional centers and institutes are renowned for the application of scientific evidence to national and international policy. Tufts University, located on campuses in Boston, Medford/Somerville, and Grafton, Massachusetts, and in Talloires, France, is recognized among the premier teaching and research universities in the U.S. Learn more at nutrition.tufts.edu/*

*The **National Produce Prescription Collaborative** (NPPC) is a collaborative of stakeholders that are working to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions (PRx) to improve health outcomes, equity, and costs within the healthcare system. PRx is a clinical treatment and preventative service for patients who are eligible due to diet-related health risk or condition and food insecurity or other challenges in accessing nutritious foods. Eligible patients are enrolled by a healthcare provider or managed care organization. PRx are filled through food retail systems and networks and enable patients to access healthy produce at low or no cost to the patient.*

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[1] New York State Department of Health, New York State Medicaid Redesign Team (MRT) Waiver Amendment at 27 (Sept. 2, 2022), https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ny-medicaid-rdsgn-team-pa-09152022.pdf.

[2] *See also* Eat Well, *Recommendations for Serving Medicaid Members in the Healthy Opportunities Pilots*, https://www.eatwellrx.org/nc-1115 (last visited Apr. 19, 2023).

[3] The HHS Office for Civil Rights 2021 proposed rule, which would codify application of the HIPAA treatment exception to social service organizations, would not fully address the issues identified here. *See* Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement, 86 Fed. Reg. 6446 (proposed Jan. 21, 2021).

[4] Kurt Hager et al., *Association of National Expansion of Insurance Coverage of Medically Tailored Meals with Estimated Hospitalizations and Health Care Expenditures in the US*, 5 JAMA Network Open e2236898 (2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2797397 (doi:10.1001/jamanetworkopen.2022.36898).

[5] Centers for Medicare & Medicaid Services, Addressing Health-Related Social Needs in Section 1115 Demonstrations (Dec. 6, 2022), https://www.medicaid.gov/medicaid/downloads/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf.

[6] *See, e.g.*, Erika Hanson et al., Center for Health Law and Policy Innovation, Building Partnerships to Advance Nutrition in California's CalAIM Waiver (Jan. 31, 2023), https://www.healthlawlab.org/2023/01/harvard-health-law-lab-case-studies-pinpoint-early-successes-challenges-of-californias-innovative-medicaid-program/.
[7] Erika Hanson et al., Center for Health Law and Policy Innovation, Building Partnerships to Advance Nutrition in California's CalAIM Waiver, Case Study: Project Angel Food and L.A. Care Health Plan (Jan. 31, 2023), https://www.healthlawlab.org/wp-content/uploads/2023/01/WPC-Case-Study-PAF-and-LA-Care_Final-Design.pdf.
[8] *See* Cindy Mann, Anne O'Hagen & Karl Heather Howard, *CMS Updates Its Budget Neutrality Policy*, Health Affairs Forefront (Jan. 26, 2023) https://www.healthaffairs.org/content/forefront/cms-updates-its-budget-neutrality-policy (doi: 10.1377/forefront.20230123.97337).
[9] North Carolina Department of Health and Human Services, Healthy Opportunities Pilot: PHP-Network Lead Model Contract (updated Oct. 2021), https://www.ncdhhs.gov/php-network-lead-model-contract/open; North Carolina Department of Health and Human Services, Healthy Opportunities Pilot: Network Lead-HSO Model Contract (updated Oct. 2021), https://www.ncdhhs.gov/network-lead-hso-model-contract/open.
[10] *See, e.g.*, Testimony of Alissa Wassung, New York 1115 Waiver Amendment: Making Targeted, Evidence-Based Investments to Address the Health Disparities Exacerbated by the COVID-19 Pandemic (May 10, 2022), https://www.health.ny.gov/health_care/medicaid/redesign/med_waiver_1115/2022-05-10_transcript.htm.
[11] *See also* Eat Well, *Recommendations for Serving Medicaid Members in the Healthy Opportunities Pilots*, https://www.eatwellrx.org/nc-1115 (last visited Apr. 19, 2023).
[12] Centers for Medicare & Medicaid Services, Addressing Health-Related Social Needs in Section 1115 Demonstrations (Dec. 6, 2022), https://www.medicaid.gov/medicaid/downloads/addrss-hlth-soc-needs-1115-demo-all-st-call-12062022.pdf.
[13] California Department of Health Care Services, CalAIM Data Guidance: Billing and Invoicing between ECM/ Community Supports Providers and MCPs (Jan. 2022), https://www.dhcs.ca.gov/Documents/MCQMD/ECM-and-Community-Supports-Billing-and-Invoicing-Guidance.pdf.
[14] Erika Hanson et al., Center for Health Law and Policy Innovation, Building Partnerships to Advance Nutrition in California's CalAIM Waiver (Jan. 31, 2023), https://www.healthlawlab.org/2023/01/harvard-health-law-lab-case-studies-pinpoint-early-successes-challenges-of-californias-innovative-medicaid-program/.