The Honorable Dr. Mehmet Oz
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850
(Submitted electronically to regulations.gov)

September 12, 2025

RE: Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz:

On behalf of the Food is Medicine Coalition (FIMC), we would like to thank you for this opportunity to provide comments on the proposed rule, "Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program" and provide recommendations focused on food is medicine (FIM) interventions.

The Food is Medicine Coalition (FIMC) is the national coalition of nonprofit organizations that provide the medically tailored meal (MTMs) and medically tailored grocery (MTGs) interventions, combined with medical nutrition therapy and nutrition counseling and education to people in communities across the country who are living with severe, complex, and chronic conditions. FIMC agencies created the MTM intervention as a response to community need forty years ago and maintain the nutrition and program standards for the intervention through the first-ever accreditation standard for the medically tailored meal intervention: the FIMC Medically Tailored Meal Accreditation Criteria and Requirements (MTM ACR). MTMs and MTGs are disease treatments that fulfill a prescribed diet, targeting nutrition as a clinical intervention to help prevent, manage, and treat a variety of conditions and complications of conditions.

As longtime advocates for policy initiatives that address the connection between nutrition and health, we are deeply appreciative of CMS's leadership over the last decade to explore

options to broaden access to evidence-based, FIM interventions in both the Medicaid and Medicare programs. Diet-related chronic health conditions, including heart disease, cancer and diabetes are the leading cause of mortality and morbidity in the United States, contributing to the deaths of nearly 1.5 million people each year and accounting for approximately 85% of our $4.5 trillion in annual health care expenditures.[1] Poor nutrition is a leading, direct determinant of health – and as such, should be appropriately addressed by the health care system, similar to smoking, poor mental health, and substance use. Food is Medicine (FIM) interventions have emerged as an important component of state and federal strategies to address the root causes of chronic disease as well as rising health care costs and other multifaceted priorities.[2] FIM interventions encompass a spectrum of nutrition services—including medically tailored meals (MTMs), medically tailored groceries (MTGs), and produce prescriptions (PRx)—which are designed to meet patient needs and are integrated into the health care system through referrals from medical providers.[3]

FIM interventions are distinct from, but complementary to, efforts to support enrollment or participation in federal and state safety net programs as well as programs that address social determinants of health (e.g., housing, education, transportation, social services). FIM directly responds to challenges with accessing and consuming foods that are indicated for conditions, which are a major barrier to population adherence to dietary recommendations. FIM interventions also respond to public demand for participating in programs that provide healthy foods to prevent, manage, and treat many diseases.[4]

For the reasons detailed above, we applaud CMS's inclusion of a Request for Information (RFI) regarding strategies to improve prevention and management of chronic disease—especially through the provision of MTMs—in the notice of proposed rulemaking for the CY 2026 Physician Fee Schedule. In response to the questions outlined in that RFI, we provide the following recommendations:

Medically Tailored Meals: The Evidence and Gaps in Access

1. *Should CMS consider creating separate coding and payment for medically tailored meals, as an incident-to service performed under general supervision of a billing practitioner?*

Yes, CMS should create separate coding and payment for medically tailored meals (MTMs) as an incident to service performed under general supervision of a billing provider and consider allowing Registered Dietitian Nutritionists (RDNs) to bill directly for the MTM service when specific requirements are met. Such a change would both reflect current evidence of impact and address a critical gap in access to medically tailored nutrition in the Medicare program.

a. Description of the intervention and evidence

The Medically Tailored Meal (MTM) intervention is the comprehensive process of delivering meals to individuals living with severe, complex or chronic condition(s) using therapeutic, evidence-based dietary specifications for conditions, based on an assessment of the

individual's nutrition needs by an RDN or other nutrition professional. While FIMC agencies welcome referrals from a variety of sources, client eligibility is verified through the involvement of health care personnel by confirmation of medical diagnoses using the most current International Classification of Diseases (ICD) diagnosis codes or medical necessity as determined by health care authorization. Once the eligibility assessment is complete, an intake and nutrition risk screening is conducted by the MTM provider. After onboarding, an RDN or other nutrition professional[5] conducts a nutrition assessment, which leads to the determination of the meal and care plan tailored for the specific circumstances of the client. Meals are prepared by the provider organization, prioritizing whole ingredients—like produce, whole grains, and lean proteins— and free from artificial preservatives, artificial colors, and artificial sweeteners. Meals are home-delivered, shipped or available for pick-up. The client is reassessed for eligibility and nutrition need at least annually. Importantly, the client has ongoing access to medical nutrition therapy, nutrition counseling, and nutrition education throughout the term of service.

A growing body of evidence demonstrates that the MTM intervention is a cost-effective approach to treating, managing, and/or preventing severe, complex and chronic disease(s) which are often diet-related, with research showing impacts across a range of nutrition (e.g., dietary intake/quality), clinical (e.g., HbA1c), and health care utilization metrics (e.g., hospitalizations). **For full outline/citation of these studies, see Appendix A.** Specifically, recent studies show the following results:

- **Three separate randomized controlled trials** providing medically tailored meals to **patients with heart failure** (ranging from 1 – 6 months) all found ~ **50% reduction in hospitalizations** among those receiving MTMs.[6,7,8]
- A **6-month program for HIV patients found an 80% reduction in hospitalizations**.[9]
- Among a sample of **dually eligible Medicare and Medicaid beneficiaries**, home delivery of medically tailored meals (10 weekly meals, plus snacks) was associated with **70% fewer emergency department visits, 72% fewer uses of emergency transportation, 52% fewer inpatient admissions, and 16% net lower health care costs** compared to matched nonparticipants. Importantly, **healthcare cost reductions were estimated to offset meal program costs, resulting in cost savings**.[10]
- For patients with **cirrhosis with ascites, a randomized trial** providing MTMs for 12-weeks **reduced the number of paracenteses and reduced mortality**.[11]
- A cohort study of 1,020 **medically complex adults across insurance types** found that the participation in an MTM program, receiving 10 weekly meals (median duration of 9 months) was associated with **49% fewer inpatient admissions, 72% fewer admissions to skilled nursing facilities, and 16% lower health care costs**, compared to not participating in the MTM program. This program was also found to produce net cost savings for payers.[12]

As a result of this evidence, researchers have been able to model the impact of nationwide provision of MTMs to individuals with diet-related conditions and limitations in activities of daily living in Medicaid, Medicare, and commercial insurance. Below, we cite the Medicare-specific results:

- **National implementation of medically tailored meals for all eligible patients in Medicare** (2.57 million Americans who have both a major diet-related condition and limited ability to perform activities of daily living) is **estimated to prevent over 700,000 hospitalizations and produce $3.4 billion in cost savings for Medicare annually, even after paying for the costs of the meals.**[13]

Finally, recent evaluations of demonstration projects in Medicaid add further weight to implementation recommendations. Both studies described below assessed the combined effects of various Food is Medicine programs authorized under the states' section 1115 demonstrations, which included MTMs:

- The Massachusetts Medicaid and Children's Health Insurance Program allowed FIM programs delivered in partnerships with social service organizations under its section 1115 demonstration waiver. A recent evaluation of the effects of the provision of nutrition on health care use and costs during the first three-year program cycle (January 2020–March 2023) analyzed data on 20,403 participants from seventeen accountable care organizations. **Program participation was associated with a 23% reduction in hospitalizations and a 13% reduction in emergency department visits** compared with the number of hospitalizations and visits for 2,108 eligible nonparticipants. **Health care costs were $2,502 lower** among adults with >90days of enrollment.[14]
- Under North Carolina Medicaid's section 1115 demonstration waiver, the Healthy Opportunities Pilots (HOP) allowed services that included nutrition supports (such as healthy food boxes, produce prescriptions, or medically tailored meals), financed by Medicaid, in 3 regions of North Carolina. Evaluation of 13,000+ HOP participants and 73,000+ comparison members showed that **Medicaid spending for HOP participants was lower by $85/person/month and achieved cost savings by 8 months** after starting the program, even accounting for costs of the nutrition supports. Emergency department visits were also lower for HOP participants.[15]

b. Current status of access to medically tailored meals in Medicare

Despite this evidence of impact, access to medically tailored meals remains limited for Medicare beneficiaries. Currently, Medicare Parts A and B do not provide any benefit or other mechanism for coverage of MTMs. Instead, such meals are only available as general supplemental benefits[16] or Special Supplemental Benefits for the Chronically Ill (SSBCI)[17] provided at the discretion of individual plans in Medicare Part C. This distinction results in a significant gap in access, with the 46%[18] of Medicare participants enrolled in Original Medicare (i.e., Medicare Parts A and B) left without any access to MTMs, and access also varying by plan for the 54% of participants enrolled in Medicare Part C. This coverage gap stands out against statistics about disease incidence in the population: As of 2023, 78.8% of older adults reported having multiple chronic conditions.[19]

By establishing separate coding and payment for MTMs as a covered service within Medicare Part B, CMS could begin to address this longstanding access gap and create

internal consistency across the Medicare program, ensuring increased access to a standardized MTM benefit for all qualifying enrollees.

MTM Service Description and Patient Circumstances

2. *If so, what would be the appropriate description of such a service, and under what patient circumstances (that is, after discharge from a hospital)?*

    a. **Service Description**

In section 1., we fully define the MTM intervention from beginning to end. For use in health care billing and coding, the Food is Medicine Coalition recommends the following description of an MTM: a meal, providing an estimated 1⁄3 of the recommended dietary intake(s), per therapeutic, evidence-based dietary specifications for conditions, assigned based on an assessment of the individual's nutritional needs by a Registered Dietitian Nutritionist (RDN) or other nutrition professional, intended for use in non-facility/home settings. This description is consistent with the MTM code submission[20] from the Coding4Food (C4F) project, a community-informed initiative aiming to create new Healthcare Common Procedural Coding System (HCPCS) codes to define a spectrum of Food is Medicine interventions in a consensus-building process with experts from across the country, facilitated by the Gravity Project. The recommended code for MTM was created, along with separate recommended codes for Medically Tailored Groceries, Healthy Groceries and Produce Prescriptions.

In addition to this description of an MTM, FIMC has publicly issued Medically Tailored Meal Nutrition Standards—a set of therapeutic, evidence-based nutrition guidelines for specific medical conditions—for use in preparing MTMs. These guidelines are updated continuously by the FIMC Clinical Committee, which is made up of RDNs from across the country, to stay current with evolving nutrition science. MTMs are prepared prioritizing whole ingredients—like produce, whole grains, and lean proteins— and free from artificial preservatives, artificial colors, and artificial sweeteners. The MTM intervention is more than delivering the correct food for a diagnosis: the client has ongoing access to medical nutrition therapy, nutrition counseling, and nutrition education.

    b. **Patient Circumstances for Service Delivery**

In establishing appropriate circumstances for service delivery, we recommend that CMS consider current practice and evidence to determine where provision of MTMs can currently be understood to be medically necessary (i.e., "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member").[21]

- **Current Practice/Precedent:** Current CMS guidance allows for coverage of meals as a supplemental benefit in Medicare Part C in two circumstances (1) "immediately following surgery or an inpatient hospital stay," or (2) "for a chronic condition . . . to transition the enrollee to lifestyle modifications."[22] This guidance provides important insight into the circumstances in which generally accepted standards of practice

indicate that meals may reasonably impact treatment of a patient's illness or injury.[23] However, this guidance is not specific to MTMs—instead capturing meals more broadly—and therefore should be combined with evidence regarding MTMs specifically to define appropriate circumstances for service delivery.

- **Current Evidence:** As of June 2025, 13 peer reviewed studies (a combination of robust quasi-experimental studies and randomized control trials) have been conducted in the United States that have evaluated changes in health outcomes and health care utilization among MTM recipients and compared those changes to a control/comparison group. To recommend the conditions for which there is currently clinical evidence supporting MTMs as medically necessary, we first rely on randomized controlled trials (RCTs) that have found improvements in clinical outcomes or health care utilization among MTM recipients.[24] However, there is also meaningful evidence from large-scale quasi-experimental studies to guide the recommendation. In particular, recent Medicaid section 1115 demonstration waiver evaluations from Massachusetts and North Carolina have shown improvements in health care utilization among MTM recipients and can support a finding of clinical evidence (as well as a finding of "generally accepted standards," given the breadth of those pilots). Taken together, this literature review indicates that current evidence supports MTM provision for patients with both advanced condition(s) (or complications of condition(s)) and food insecurity or malnutrition. (For full outline/citation of these studies, see **Appendix A**).

Combining current practice with MTM-specific evidence, we recommend that CMS allow coverage of MTMs under the following circumstances:

- Immediately following surgery or an inpatient hospital stay, OR
- Where provision of MTMs is reasonable and necessary to treat: (1) an advanced condition(s) or complications of an advanced condition(s) in an individual who is (2) at risk for poor nutrition, as measured by food insecurity, nutrition insecurity, or clinical diagnosis of malnutrition.

Within the category of "advanced condition" we would recommend coverage for the following conditions, based on current evidence and practice:

- **Excellent evidence from randomized trials:** individuals living with heart failure, HIV, or cirrhosis
- **Strong evidence from quasi-experimental studies and Medicaid demonstrations:** individuals living with uncontrolled diabetes, chronic kidney disease (stage 4 or 5), and high-risk pregnancy, or other advanced conditions, like cancer and COPD.

In developing its criteria, we encourage CMS to provide examples, such as those described above, while leaving the list non-exclusive to allow for clinical judgement to determine when provision of MTMs is medically necessary. Such flexibility is both in line with other recent services covered via incident-to authority (e.g., Principal Illness Navigation services for "serious high-risk conditions"), and reflective of the fact that the evidence base regarding

MTMs is continuing to grow, and will likely produce robust evidence showing the benefit for additional advanced conditions in the years to come.

c. Service Dose and Duration

Additionally, we recommend that CMS look to this same evidence base in establishing the appropriate dose and duration for the MTM service — especially for individuals experiencing advanced conditions. In these studies, the provision of MTMs for longer durations — at least 6 months — and in a dose of at least 10-21 meals per week was most strongly associated with health benefits. We therefore recommend that in establishing the service criteria and circumstances of coverage, CMS allow coverage of MTMs for a duration of at least 6 months, at a dose of at least 10 meals per week. Additionally, we recommend that clients are reassessed for continued eligibility for MTMs at 6-month intervals, allowing for renewal based on the above qualifying health conditions and clinical discretion of the billing provider.

Incident-to Pathway and Billing Provider

3. *Do community-based organizations providing medically tailored meals currently employ a physician, nurse practitioner, physician assistant, or other practitioner who could both bill Medicare and supervise a medically-tailored meal service?*

FIMC's membership is currently made up of 39 member organizations across 24 states and D.C. All of these members are community-based organizations, many with decades-long histories of providing high-quality MTMs and medically tailored groceries (MTGs) in the communities they serve. Typically, our member organizations do not employ Medicare practitioners with authority to bill for services provided incident to their care (i.e., physicians, nurse practitioners, certified nurse-midwives, clinical nurse specialists, clinical psychologists, or physician assistants[25]).

We do not believe this should in any way discourage CMS from moving forward with incident-to billing for MTM services. As described in response to 4., below, FIMC agencies regularly work closely with such billing providers through contractual arrangements.

Moreover, FIMC members do typically employ one or more Registered Dietitian Nutritionists (RDNs), a category of practitioners currently authorized to deliver and bill several nutrition-related services in the Medicare program, including medical nutrition therapy (MNT),[26] diabetes self-management training (DSMT) services,[27] and caregiver training.[28]

Registered Dietitian Nutritionists (RDNs) are "food and nutrition experts with a minimum of a graduate degree from an accredited dietetics program, who completed a supervised practice requirement, passed a national exam and continue professional development throughout their careers." In addition, there are specialty credentials in the field of dietetics. Board-certified specialists are credentialed by the Commission on Dietetic Registration, the credentialing agency for the Academy of Nutrition and Dietetics.

RDNs are deeply integrated into the provision of MTM services and have been involved in providing the MTM intervention since its inception, applying their expertise in nutrition to

implement the science of layering evidence-based, therapeutic dietary guidelines for conditions to care for patients with complex medical needs and dietary requirements.

At FIMC agencies, RDNs are integrated throughout the MTM intervention process. For example, RDNs:

- collaborate with kitchen staff to ensure meals adhere to the FIMC Medically Tailored Meal (MTM) Nutrition Standards, and lead food safety policies at agencies,
- complete a nutrition assessment for each client, involving review and documentation of available information such as food or nutrition-related history; biochemical data, medical tests and procedures; anthropometric measurements, nutrition-focused physical findings and client history,
- assign an appropriate meal and care plan tailored for the medical circumstances of the client,
- provide ongoing access to medical nutrition therapy, nutrition counseling, and nutrition education throughout the term of service (*medical nutrition therapy is currently covered in the Medicare program, but limited to diagnoses of diabetes, chronic kidney disease, or 36-months post-kidney transplant)[29],
- supervise RDNs-in-training, and qualified dietetic technicians, registered (DTR) within their agency, or partner with similar roles on treatment teams for clients, though RDNs are the primary provider of nutrition services.

While we recognize that RDNs do not currently have the authority to submit claims for services provided by auxiliary personnel incident to their services, we urge CMS to consider whether there are opportunities and potential benefits to recognizing RDNs as qualified billing providers who may directly bill (i.e., submit claims) for MTM services on behalf of qualified MTM provider organizations/suppliers. This approach would be similar to CMS's current recognition of the RDN as a qualified billing provider for diabetes self-management training (DSMT) services who may submit claims on behalf of a DSMT Accredited program.[30] CMS could consider piloting such an approach via the CMS Innovation Center, testing the impact of allowing RDNs to directly bill for the codes established in response to this RFI. Testing this approach via the CMS Innovation Center could also allow CMS to experiment with expanding access to medical nutrition therapy to additional diagnoses and to evaluate impact.

Alternatively, CMS could consider whether it would be possible—under current authority—to allow RDNs to engage in direct billing for MTM services when the services are a component of the treatment/care plan associated with the provision of medical nutrition therapy services via Medicare Part B Preventive Services. This approach would align with current CMS policy[31] of allowing RDNs to submit claims for new caregiver training codes when an RDN or nutrition professional "identif[ies] a need to involve and train one or more caregivers to assist the patient in carrying out a patient-centered care plan for medical nutrition therapy (MNT) services."[32]

Community-Based Organization Referral and Health Care Integration

4. *Should CMS consider allowing billing providers to refer to community-based organizations to deliver and ensure quality of medically-tailored meals while under general supervision (please see § 410.26(a)(3) for further information about general supervision) of the referring billing provider?*

Yes, CMS should allow billing providers to refer to community-based organizations to deliver and ensure the quality of medically tailored meals while under general supervision of the billing provider.

a. This flexibility is consistent with CMS precedent

In the past, CMS has allowed for billing practitioners to arrange for certain incident-to services to be provided by auxiliary personnel who are external to, and under contract with, the practitioner or their practice, such as through community-based organizations (CBOs). In these cases, CMS has allowed for general supervision, in which the services are provided under the overall direction and control of the billing practitioner, but without the billing practitioner needing to be present for the performance of the service.[33] For example, CMS has recently authorized this practice in the provision of both Principal Illness Navigation and Community Health Integration services.[34] In these cases, CMS has allowed such arrangements, provided that all of the "incident to" and other requirements and conditions for payment of the services are met and that there is "sufficient clinical integration" between the CBO and the billing practitioner.[35] In particular, to establish "clinical integration," CMS has noted its expectations that personnel performing the services would communicate regularly with the billing practitioner (to ensure the billing practitioner can appropriately document the services in the medical record) and continue to involve the billing practitioner in evaluating the continuing need for the service.[36]

b. CBO providers of MTMs regularly contract with health care providers to serve their patients.

FIMC agencies created the medically tailored meal intervention four decades ago and have a long history of delivering a high-quality MTM intervention, integrated into treatment and care via connection with health care providers.

Because of our initial focus on people living with HIV and through the evolution of agency missions to serve people living with additional illnesses over the past four decades, our community-based organizations (CBOs) have prioritized the strict protection of patient confidentiality and compliance with HIPAA privacy rules where indicated. Recognizing the severe, chronic, and often complex health conditions our clients face, our agencies have developed and maintained secure, sophisticated systems for clinical integration and data sharing, enabling seamless, referral and coordination with medical providers across care settings, regardless of whether health care is the payer for services. Specific requirements for FIMC-accredited providers on these topics can be found in Section 8 of the FIMC MTM ACR.

Our non-profit CBOs conduct extensive outreach to local health care professionals, hospital networks, community health centers and other social service providers to educate them on the nutrition services available within our network. This outreach fosters well-established referral relationships and enables providers to confidently identify individuals that need MTM or medically tailored groceries (MTGs) and direct patients to services that align with their care plans. Agencies' systems support both outbound and inbound referrals, ensuring services are delivered in close alignment with a patient's clinical needs, while protecting sensitive health information at all stages of the process.

Our agencies also depend on the clinical discretion of medical professionals to guide service eligibility, ensuring that referrals and interventions reflect the real-time assessment of a patient's health status. This trust in provider judgment reinforces the integrity of our model and protects patients from unnecessary or misaligned services.

FIMC agencies have led the drive to leverage flexibilities—largely in our public insurance infrastructure—to provide this health-promoting cost-effective service to individuals who need it. From Medicaid 1115 waivers, in lieu of services and value-based payment arrangements, to updated guidance on how best to design access in Medicare Part C, our nonprofits have advised on how to co-design pathways and guardrails for implementation of MTMs.

Finally, our network has developed the only recognized standard for the medically tailored meal intervention at the heart of this request for information: the FIMC MTM Intervention Accreditation Criteria and Requirements, or FIMC MTM ACR. FIMC agencies are known for the impressive outcomes our nutrition programs produce. We know that these results are only possible with nutritious food, community connection and a client-centered approach – all of which the FIMC MTM ACR codifies and offers to the field as a guidebook for meeting community needs. The ACR synthesizes decades of service provision into a standard for the field that ensures fidelity to the MTM intervention for nonprofits, regardless of location, size or number of clients. While the standard is rigorous, it is also flexible enough to encourage culturally relevant services that meet the nutrition needs of diverse populations. Importantly, FIMC has released this standard publicly and the nutritional guidelines incorporated in it have already made their way into policy guidance for these services in Medicaid in several states (NC, NY, MI).

FIMC agencies have created and sustained a robust framework for secure clinical care integration, and we actively share these best practices through our national, member-based technical assistance platform—setting a high bar for quality and confidentiality in service delivery across the field.

Based upon this experience—and its alignment with frameworks that CMS has used for other recently established services—we believe it is reasonable for CMS to allow billing practitioners to refer to community-based organizations to deliver and ensure quality of medically tailored meals while under general supervision of the billing practitioner.

c. This approach should be available in tandem with the suggestions under 3., above.

Singular reliance on an incident-to approach may limit uptake of the MTM service. In other contexts, such as intensive behavioral therapy for obesity (IBT), for example, referral rates for incident-to services have been notably low, with only 0.1% of eligible Medicare enrollees receiving the service in 2012 and 0.2% in 2015.[37]

Uptake may be improved, in part, by CMS's proposal to allow general, rather than direct, supervision. However, given this history, we urge CMS to also consider whether there are opportunities to build upon this incident-to approach by opening avenues to direct billing for MTM services, such as through the RDNs on staff at MTM organizations, as discussed above.

The establishment of incident-to coverage which allows for billing providers to refer to community-based organizations for service delivery under general supervision is a significant and critical first step towards addressing the current MTM access gaps in the Medicare landscape. We therefore applaud this proposal and urge CMS to move forward by formally including proposed codes for such incident-to services and related requirements in a future notice of proposed rulemaking. Where possible, though, we encourage CMS to also go a step further by establishing avenues for RDN direct billing to deepen impact and ease of implementation for this important change.

Maintaining MTM Service Integrity

5. *If CMS were to create separate coding and payment for medically tailored meals, how should CMS ensure integrity of the service being delivered?"*

We believe that standard CMS safeguards will ensure the integrity of MTM services. First, as with other incident-to services, billing providers should be required to have either an employment arrangement or a contract in place with auxiliary providers. As part of any contracting process, billing providers should credential the CBO to ensure it is qualified to provide MTM services. As explained elsewhere in this comment letter, the FIMC MTM ACR offers an example of the standards that should be included in effective credentialing—facets that demonstrate an organization's capacity for nutritionally appropriate meal design, nutrition services delivered by an RDN, food safety, and compliance with applicable regulations such as HIPAA, among other requirements.

Second, documentation requirements should allow for transparency in claims review and audits. As described elsewhere in this comment letter, the foundation has been laid for codes that specify the nature of MTM services, thereby allowing for clarity, consistency, and accuracy in billing practices. Additional appropriate service documentation in a beneficiary's medical record may include medical necessity, beneficiary consent to receive the service, a description of the treatment plan (i.e., the beneficiary's nutrition assessment, assigned meal plan, number of meals per week, and duration of the intervention including renewal periods as they occur), and confirmation of service delivery to or receipt by the beneficiary.

Additional Considerations

In addition to the specific points raised in the RFI itself, we recommend that CMS consider the following points as it moves forward in developing its MTM coverage proposal:

- **Valuation:** In creating an MTM incident-to service, CMS will need to determine valuation for payment purposes. In setting service valuation, we urge CMS to consider the full components of the intervention (e.g., nutrition assessment with an RDN or nutrition professional, meal design, meal preparation with high-quality ingredients, meal delivery) and the ways in which these components impact cost. The MTM intervention is notably more complex than standard meal services, due to the patient-centered, tailored nature of the intervention. As a result, we encourage CMS to take this complexity into account and look to examples that specifically reflect the MTM model when determining valuation. For example, some peer reviewed national modeling studies[38] have reported on average pricing across a cohort of MTM programs, and some states have set fee schedules[39] in their Medicaid programs that reflect historic data on MTM costs. These types of sources are likely to more accurately reflect the cost of the MTM service than sources describing the cost of non-tailored meals. Further, allowance should be made for differing delivery costs based on the geography of the proposed population targeted—e.g. reaching rural or outlying areas via shipping or delivery can cost more.
- **Virtual and In-Person Services**: In general, direct face-to-face interaction is not necessary for high-quality, appropriate MTM service provision. Further, allowing for different modes of service delivery—to improve accessibility—for severely ill populations is important. We recommend that CMS explicitly allow for the service, including nutrition assessments, to occur virtually, in person, or through a mix of virtual and in-person encounters.
- **Step-Down Services/Other FIM Interventions:** Additionally, we recognize MTMs are only one of a range of nutrition supports that may be an appropriate component of treatment for individuals living with diet-sensitive and other severe or complex conditions. As noted above, MTMs are a critical service for many individuals navigating advanced conditions. However, a growing body of evidence indicates that medically tailored groceries and produce prescriptions[40] can also be a beneficial component of treatment for individuals who are experiencing a diet-sensitive condition but whose needs are less acute (e.g., for individuals who are still able to shop and prepare food). We therefore encourage CMS to consider taking a similar approach to creating coverage pathways for these services to ensure that Medicare enrollees can be connected with the nutrition supports that reflect their individual level of need.
- **Cost-Sharing:** Finally, while not raised in the Request for Information, we recognize that the inclusion of MTM as a Medicare Part B service will likely result in the application of beneficiary cost-sharing requirements (20% coinsurance). Historically, FIMC agencies and their healthcare partners have not imposed cost-sharing on their MTM services, and there is concern that cost-sharing poses a potential deterrent to service uptake. While FIMC agencies largely don't have income-based eligibility

criteria for service, most of FIMC clients live at or below the federal poverty level. Additionally, FIMC clients may already manage higher than average health care costs due to the severity of their complex and/or chronic health condition(s). Given the potential hardship that this could pose to MTM recipients—and the barrier it could present to uptake of this important intervention—we urge CMS to explore options to eliminate cost-sharing for this service, or, at a minimum, work with other regulators as appropriate to provide guidance on sliding fee scales, co-insurance waivers, and other strategies to alleviate out-of-pocket costs for beneficiaries.

Conclusion

Thank you for allowing us to provide comments on this important Request for Information. We welcome additional opportunities to communicate with you, and please do not hesitate to contact me at awassung@fimcoalition.org if you have any questions or issues for discussion.

Sincerely,

Alissa Wassung
Executive Director
Food is Medicine Coalition

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[1] US Burden of Disease Collaborators, The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States, 319(14) JAMA 1444 (2018), https://doi.org/10.1001/jama.2018.0158; United States Government Accountability Office, Chronic Health Conditions: Federal Strategy Needed to Coordinate Diet-Related Efforts (Aug. 2021); US Centers for Disease Control and Prevention, Fast Facts: Health and Economic Costs of Chronic Conditions (July 12, 2024).

[2] Dariush Mozaffarian et al., "Food is Medicine" Strategies for Nutrition Security and Cardiometabolic Health Equity: JACC State-of-the-Art Review, 83 J. AM. COLL. CARDIOL. 843 (2024), https://www.jacc.org/doi/10.1016/j.jacc.2023.12.023.

[3] U.S. Department of Health and Human Services, Food Is Medicine Landscape Summary (Sept. 2024); Kurt Hager et al., Aspen Institute, Food is Medicine Research Action Plan (2024).

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[5] *See* 42 U.S.C. § 1395x(vv) (defining RDN and nutrition professional).

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Annex A: Evidence for Health Benefits in Peer-Reviewed Medically Tailored Meal Studies

This table outlines medically tailored meal (MTM) studies with comparison groups that evaluated health outcomes and healthcare utilization. These include randomized trials and quasi-experimental studies. Several studies included multiple diagnoses as eligibility criteria; thus the effects should be interpreted as pooled effects across multiple conditions. Other studies focused exclusively on a single medical condition. Diagnoses included in previous MTM studies that assessed changes in health outcomes and healthcare utilization are below:

1. High healthcare utilization (recent hospitalization or high ED visits)[1-5]
2. Diabetes[2,5-8]
3. Need for assistance with instrumental activities of daily living[5,7,8,13]
4. Heart failure[2,3,9]
5. HIV[10,13]
6. Cirrhosis[11]
7. High-risk pregnancy[5,12]

Food is Medicine Intervention	Strength of Evidence	Intervention duration	Intervention dose	Foods selected	Nutrition education
Medically tailored meals (MTM)	Several quasi-experimental studies on medically tailored meals, which are often prioritized for medically complex patients with activity limitations and provided meals for 6 months -2 years, have found reductions in hospitalizations, ED visits, and healthcare costs.[7,8,13] Trials seeking to confirm these findings have had mixed results. A 6-month program for HIV patients found an 80% reduction in hospitalizations,[10] a 6-month trial for heart failure patients found a 50% reduction in hospitalizations, and 10-week program found a 50% reduction in hospitalizations among heart failure patients only, but not patients with diabetes or kidney	Studies that provided meals for longer durations found reduced healthcare utilization. Receiving meals for at least 6 months has the strongest evidence in both large quasi-experimental studies and trials. [5,7,8,10, 13] Very short meal programs of 2-4 weeks did not reduce healthcare utilization,[4] and a 10-week program for patients with diabetes and chronic kidney disease also did not reduce healthcare utilization (actual average meal time was 7 weeks).[11]	Studies that provided 10-21 meals per week found greater benefits.[3,5,7,8,10] Programs that provided only 1 meal per day for 5 days per week (half the dose included in other studies), found less or no impact.[2,4]	Meals are designed by registered dietitians to meet nutritional needs of specific diagnoses and vary across heart failure, kidney disease, cirrhosis, etc.	Several programs had optional nutrition counseling with 1-3 sessions with a RDN.

	disease.[2] MTM programs of very short duration (2 and 4 weeks), have not found any impact on healthcare utilization and costs in trials.[4] There is evidence that programs implemented during the COVID-19 emergency period were less effective.[5] For HIV patients, MTMs reduced hospitalizations by 80% and improved mental health, but had no impact on viral suppression.[10] For patients with cirrhosis with ascites, MTMs for 12-weeks reduced the number of paracenteses and reduced mortality.[11] In work currently under review and conducted by Tufts and UMass investigators, MTM recipients with greater comorbidity (DxCG score) experienced the largest reductions in healthcare costs.	A 3-month meal program for Medicaid members with diabetes did not find an impact on HbA1c at 6-months after randomization (ie, 3-months after meals ended during a 3-month meal program).[6] The exception is for heart failure patients, wherein three RCTs have found ~ 50% fewer hospitalizations among heart failure patients receiving MTMs, 2 of which were for shorter durations of 4-10 weeks after hospital discharge, while a third provided meals for 6 months.[1,2,9]			
MTM pooled effects with medically tailored groceries (MTG) & produce prescriptions	Two recent studies on Medicaid 1115 Waivers in MA and NC pooled 20,000 and 14,000 patients receiving a range of Food is Medicine programs for analysis. Most of the programs were either MTGs or produce prescriptions, with some MTMs. In MA, 20,000 Medicaid members enrolled in the Flexible Services nutrition program experienced 23% fewer	Most programs were designed to be 6-months, with an opportunity to re-enroll based on physician recommendation. In the MA study, longer enrollments were associated with greater reductions in healthcare utilization and costs.[5] In NC, cost savings occurred 8 months after referral to	Varied widely, but in general MTG and MTMs provided 10 meals / week, produce prescriptions and food vouchers provided ~ $100/month.	Varied, but in general foods were fruits and vegetables or meals / groceries designed by RDNs to meet medical needs.	Varied widely. Some programs offered nutritional education but it was not a requirement in either 1115 Waiver.

	hospitalizations and 13% fewer emergency department admissions.[5] Significant healthcare cost reductions were observed after the height of the COVID-19 pandemic in years 2022-23 (offsetting 75% of the program costs) and among adults enrolled for 3 months or longer across all study years (2020-2023), resulting in cost savings.[5] In NC, 14,000 Medicaid members enrolled in the Healthy Opportunities Pilots experienced fewer ED visits and lower medical spending. The program resulted in cost savings to NC Medicaid after 8 months of HOP receipt. In NC, HOP recipients had fewer ED visits, but there was no change in hospitalizations.	the Healthy Opportunities Pilot program.[12]			

**Additional MTM studies not included in this table have found improvements in dietary quality, food insecurity, medication adherence, and mental health (Kelly 2023, Belak 2022, Sakr-Ashour 2021, Berkowitz 2020, Berkowitz 2019, Palar 2017, DiMaria-Ghalili 2015).*

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