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/.