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

July 3, 2023

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted electronically to regulations.gov

Attn: Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality Proposed Rule (CMS–2439–P)

Dear Administrator Brooks-LaSure:

The Center for Health Law and Policy Innovation of Harvard Law School (**CHLPI**) appreciates the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (**CMS**) proposed rule on Medicaid and Children's Health Insurance Program Managed Care Access, Finance, and Quality (CMS–2439–P) (**the Proposed Rule**).

CHLPI advocates for reforms to improve the health of underserved populations, with a focus on the needs of low-income people living with chronic conditions. We have an active portfolio dedicated to addressing unmet health-related social needs (**HRSN**) through health care delivery and financing. While many HRSN interventions can have a powerful impact on health outcomes, disparities, and costs, the availability of these services is often limited by lack of sustainable health care funding and regulatory barriers. CHLPI works with stakeholders including health systems, private and public health plans, community-based organizations (**CBOs**), and government officials across the country to drive health system reform that better supports these innovative and equitable health care solutions.

Given its dominant role in delivering health care to the populations we serve, a central aspect of our work involves analysis of, education on, and advocacy for increased access to HRSN services through Medicaid Managed Care. In the wake of the COVID-19 pandemic – which deepened widespread inequities in food insecurity and chronic conditions – and the second-ever White House Conference on Hunger, Nutrition and Health, we have seen particular interest in addressing nutrition through Medicaid Managed Care.[1] Aligned with the focus of this Proposed Rule, legal and regulatory barriers that limit equitable service access, impact, and value are often front-and-center in our conversations with stakeholders working to improve patient health and well-being through these pathways.

[1] *See, e.g.,* KRISTIN SUKYS ET AL., CENTER FOR HEALTH LAW AND POLICY INNOVATION, MAINSTREAMING PRODUCE PRESCRIPTIONS IN MEDICAID MANAGED CARE: A POLICY TOOLKIT AND RESOURCE LIBRARY (June 2023), https://chlpi.org/wp-content/uploads/2023/06/Mainstreaming-Produce-Prescriptions-in-Medicaid-Managed-Care-V6.pdf; THE FOOD TRUST, POPULATION HEALTH ALLIANCE & CENTER FOR HEALTH LAW AND POLICY INNOVATION, ADDRESSING NUTRITION AND FOOD ACCESS IN MEDICAID (Jan. 2022), https://populationhealthalliance.org/wp-content/uploads/2022/01/addressing_nutrition_foodaccess_Jan2022.pdf.

We have focused our comments on recommendations and considerations that we hope will further our shared goals.

1. **Population-Based and Condition-Based State Directed Payments – Proposed Amendments to Section 438.6(c)**

We applaud the inclusion of a regulatory framework that will allow for the approval of value-based payment (VBP) initiatives that further innovations in patient-centered care and delivery system reform with the goals of making our health system more equitable, outcome-driven, and cost-effective. Our hope is that by allowing for the use of population-based and condition-based payments in state-directed payment (SDP) arrangements, more states will be encouraged to adopt innovative VBP initiatives to address the social determinants of health. For example, New York's Value Based Payment Roadmap requires contractors in certain agreements to implement at least one intervention that addresses a HRSN, such as housing instability, food insecurity, or transportation problems. We suggest that any SDP rates 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.

2. **In Lieu of Services and Settings (ILOS) – Proposed Amendments to and Additions at Sections 438.2, 438.3, 438.7, 438.16, 438.66**

CHLPI further applauds CMS for proposing to codify in regulation many key pieces of its January 2023 State Medicaid Director Letter on Use of In Lieu of Services and Settings in Medicaid Managed Care.[2] We share the sentiments expressed in the Proposed Rule regarding the promise of ILOS to address unmet needs in underserved communities. Several stakeholders with whom we work are interested in ILOS as a pathway to support HRSN services, particularly in states and localities where statewide pathways for sustainable funding, such as 1115 and 1915(b) waivers, may not be politically, fiscally, or administratively viable options. We also support delivery of these services through Medicaid managed care plan partnerships with local CBOs and providers. Finally, we are supportive of appropriate monitoring and oversight to ensure equitable access, utilization, transparency, and cost-effectiveness.

A. Cost Percentage and Actual Cost

Beyond the information the Proposed Rule already requires to be published (e.g., enrollee rights and protections, the name and definition for each ILOS and the State Plan-covered service or setting for which it is substituted), where possible, we suggest that CMS make ILOS reporting publicly available. Aggregating the evidence to establish that a service or setting is a medically appropriate, cost-effective substitute and then establishing the actuarial model for ILOS may be a daunting task for Medicaid agencies or plan staff. However, if CMS has approved an ILOS or state model, publicizing this information could reduce the burden for states and managed care plans looking to utilize similar alternative services and settings. For example, under section 438.16(c) of the Proposed Rule, states must annually calculate "the projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and

[2] CENTERS FOR MEDICARE & MEDICAID SERVICES, SMD #: 23-001 Re: Additional Guidance on Use of In Lieu of Services and Settings in Medicaid Managed Care (Jan. 4, 2023), https://www.medicaid.gov/federal-policy-guidance/downloads/smd23001.pdf.

PAHP ILOS costs" – this information could be valuable to stakeholders looking to replicate ILOS schemes in their states or plans.

B. Capitation Rates

We appreciate the Proposed Rule's emphasis on actuarially sound capitation rates, 42 C.F.R. § 438.4(a). We also support the Proposed Rule's codification of previous guidance that ILOS can be used when "expected to reduce or prevent the future need to utilize the covered service or setting," at section 438.2. While ILOS are required to be cost-effective substitutes, as the Proposed Rule acknowledges,[3] those alternative services and settings which are expected to reduce future need for State Plan services may not produce returns on investment immediately. (This is not to imply that these services do not produce returns on investment or that many do not show cost-effectiveness or efficiency within a short time).[4] Therefore, actuarily sound capitation rates should take these factors into account to ensure that rates adequately support the projected costs of providing ILOS, particularly in the first years of implementation.

C. Medical Appropriateness

From our experience working with CBOs providing HRSN services and other stakeholders implementing ILOS and other large-scale managed care programs, it is imperative that those with knowledge of the services at issue – whether physicians, nurses, social workers, CBOs, beneficiaries, etc. – are meaningfully included in the process of defining the "clinically defined target populations" and eligibility criteria for services, proposed at section 438.16(d)(1)(iii). The input of these stakeholders is essential for a successful program in which beneficiaries have equitable access to high-quality services and in which utilization, return on investment, and patient satisfaction are high.

CHLPI also supports processes which allow plan staff providers to determine that an ILOS is medically appropriate for enrollees based on medical records and documentation. These processes allow HRSN services to reach enrollees who are disconnected from the traditional health care system.

D. Reporting, Monitoring, and Evaluation

The use of ILOS to address HRSN is still a nascent and developing field, with only eight states using at least one ILOS to address the social determinants of health. And while partnerships between Medicaid managed care plans and CBOs to deliver these services are developing

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[3] 88 Fed. Reg. 28092, 28230.

[4] *See, e.g.,* 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 (nationwide adoption of medically tailored meals would prevent an estimated 1.6 million hospitalizations and save payers a net $13.6 billion in the first year); Julian Xie et al., *The Impact of a Produce Prescription Programme on Healthy Food Purchasing and Diabetes-Related Health Outcomes*, 24 PUBLIC HEALTH NUTR. 3945 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8369461/ (doi: 10.1017/S1368980021001828); 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.

throughout the country, scaling successful programs takes time and infrastructure investment.[5] Therefore, we caution that the burdens of reporting, monitoring, and evaluation of ILOS be carefully considered so as to continue to encourage the use of ILOS as a flexible tool for innovation. For example, we are concerned that evaluation requirements similar to those of 1915(b) waivers – without the fiscal benefits that a waiver pathway provides – may deter plans and/or states from utilizing ILOS to the Proposed Rule's full preventive, cost-effective, and equitable potential.

We encourage simplification and streamlining of reporting, monitoring, and evaluation requirements. For example, we support including the ILOS cost percentage with the rate certification, section 438.16(c)(5)(i), and likewise aligning all other reporting, monitoring, and evaluation processes with existing Medicaid managed care required processes where possible. Where this is not possible, we suggest combining reporting, monitoring, and evaluation across all managed care programs (if less burdensome for reporting entities). For example, we suggest any evaluation, such as the retrospective evaluation currently proposed at section 438.16(e)(1), be reported across all managed care programs – which will also allow for larger sample sizes.[6] Finally, we support proposals which would streamline reporting, monitoring, and evaluation, such as the proposal at section 438.16(d)(1)(vi) to require that states include a contractual requirement that managed care plans utilize specific codes to identify each ILOS in enrollee encounter data. In addition to encouraging states to work towards the development of CPT and HCPCS codes with the collaboration of stakeholders, we ask that CMS coordinate and support these efforts[7] on the federal level so as to avoid redundancy, duplication of investments, and conflicting codes across states.

3. Managed Care State Quality Strategies – Proposed Amendments to Section 438.340

CHLPI supports the proposed amendments at section 438.340, which would require states to make their quality strategy available for public comment at 3-year renewal and post the results of its 3-year review to its website. Quality strategy reporting requirements, objectives, and performance measures offer an important tool for stakeholders to ensure that states and Medicaid managed care plans are addressing metrics related to the social determinants of health and health inequity, such as transportation, food insecurity, and diet-related diseases. But state Medicaid agencies have different approaches to providing public access to metrics and reports regarding their programs. This proposal goes a long way towards providing transparency for interested parties.

4. Medicaid Managed Care Quality Rating System, Mandatory Measure Set – Proposed Additions at Section 438.510

CHLPI appreciates CMS's extensive consultation and development process in selecting the proposed initial set of 18 measures for the Medicaid and CHIP Quality Rating System (MAC QRS). We urge CMS to consider specifically including an equity measure, such as 'screening

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[5] *See, e.g.,* ERIKA HANSON ET AL., CENTER FOR HEALTH LAW AND POLICY INNOVATION, BUILDING PARTNERSHIPS TO ADVANCE NUTRITION IN CALIFORNIA'S CALAIM WAIVER (June 29, 2023), https://www.healthlawlab.org/2023/06/building-partnerships-to-advance-nutrition-in-californias-calaim-waiver-a-case-study-series/.

[6] In the first nine months of California's statewide ILOS waiver, just over 27,000 enrollees had received services, https://www.dhcs.ca.gov/CalAIM/Documents/ECM-and-CS-Fact-Sheet-Q1-Q3.pdf.

[7] Efforts are already underway, see, https://www.spur.org/events/2022-09-30/back-basics-medical-coding-food-based-interventions.

for social drivers/social needs screening and intervention', which is included in the Universal Foundation.[8] We also urge CMS to include 'follow-up to address identified social needs', as indicated for future inclusion in the Universal Foundation.[9] CMS has solicited feedback on including these and similar HEDIS measures in Medicare Quality Strategy and STAR Ratings measures.[10] The social determinants of health underlie disparities in the incidence and outcomes of diseases and conditions that CMS prioritizes in the proposed MAC QRS mandatory measure set, including diabetes,[11] high blood pressure,[12] and cancer,[13] and without specific measures of HRSN, these Medicaid patients will be left behind. Need among these patients is pressing: a study of 27,400 individuals in a Massachusetts Medicaid ACO, conducted between February 2019 and February 2020, found that roughly 45% of respondents reported one or more social risk factor.[14]

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CHLPI applauds CMS's commitment to equitable service access, beneficiary utilization, and enrollee experience. We appreciate this opportunity to offer our feedback and would be happy to work with CMS to further address any of the comments above. Please contact Erika Hanson at ehanson@law.harvard.edu with questions.

Sincerely,

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Clinical Instructor

on behalf of

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[8] Douglas B. Jacobs et al., Aligning Quality Measures across CMS—The Universal Foundation, 388 NEJM 776-779 (2023), https://www.nejm.org/doi/full/10.1056/NEJMp2215539.
[9] *Id.*
[10] *See* CENTERS FOR MEDICARE & MEDICAID SERVICES, Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Feb. 1, 2023), https://www.regulations.gov/document/CMS-2023-0010-0001.
[11] *See, e.g.*, Victoria L. Mayer et al. Food Insecurity, Coping Strategies and Glucose Control in Low-Income Patients with Diabetes, 19(6) PUB. HEALTH NUTRITION 1103, 1105 (2015), https://perma.cc/SF99-P9SV.
[12] *See, e.g.*, Craig Gunderson & James P. Ziliak, The Health Consequences of Senior Hunger in the United States: Evidence from the 2019-2014 NHANES, Feeding America & The Nat'l Found. to End Senior Hunger, 3, 7 (2017), https://perma.cc/JN9H-ZASM.
[13] *See, e.g.*, Fang Fang Zhang et al. Preventable cancer burden associated with poor diet in the United States, 3(2) JNCI CANCER SPECTRUM pkz034 (2019), https://pubmed.ncbi.nlm.nih.gov/31360907/.
[14] Katherine H. Schiavoni et al., Prevalence of social risk factors and social needs in a Medicaid Accountable Care Organization (ACO), 22 BMC HEALTH SERVICES RESEARCH 1375 (Nov. 2022), https://doi.org/10.1186/s12913-022-08721-9.