February 6, 2023

Christi A. Grimm
Inspector General
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Grimm:

As participants in the recent 2022 White House Conference on Hunger, Nutrition, and Health, the Center for Health Law and Policy Innovation of Harvard Law School and the Gerald J. and Dorothy R. Friedman School of Nutrition Science and Policy of Tufts University applaud the critical commitments made by the Department of Health and Human Services ("HHS" or the "Department"). Meaningful progress towards the goal of better integrating nutrition and health will require engagement by bodies across the Department. **We write today to raise up a pivotal role of the HHS Office of Inspector General ("OIG"): enabling a broad range of Food is Medicine interventions to be delivered without violating the Anti-Kickback Statute ("AKS") or the beneficiary inducements prohibition of the Civil Monetary Penalties Law ("CMPL").**

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. **Challenges navigating AKS and CMPL (collectively referred to herein as "inducement prohibitions") are often front-and-center in our conversations with health care system and community-based provider stakeholders interested in partnering to improve patient health and well-being.** CHLPI strives to respond to the need for inducement prohibitions-related technical assistance through various efforts, including educational sessions targeting regulatory compliance counselors and the development of a comprehensive resource for food banks on navigating these concerns when partnering with health care organizations to address food insecurity. During the height of COVID-19, we helped translate and disseminate emerging OIG guidance to those who needed it.

Researchers at Tufts are among those in the nation leading the evaluation of Food is Medicine programs, demonstrating the tremendous impact such interventions have on health care utilization, costs, and outcomes, and informing strategies to address nutrition-related needs. At present, the Tufts Friedman School of Nutrition Science and Policy has 11 research projects focused on Food is Medicine, with additional projects pending or planned. Topics of these projects include assessing public perception of programs; estimating the health impacts, costs, and effects on disparities in various Food is Medicine programs; partnering with small- and medium-sized farms to connect health care providers with produce boxes; and evaluating the potential benefits of Food is Medicine programs to specific patient populations, including individuals who are pregnant and

individuals who have diet-related chronic diseases. Tufts' policy research in these areas has contributed to, for example, the establishment of a new, bipartisan Food is Medicine Working Group within the U.S. House Hunger Caucus to elevate and highlight the intersections between hunger, nutrition, and health; the Working Group's organization of several Congressional Briefings on key topics; and introduction of proposed legislation around Food is Medicine, such as a bill for HHS to test medically tailored meals in Medicare populations. Tufts also helped found the National Produce Prescription Collaborative (NPPC) in spring 2019, a group that has worked to embed and institutionalize Produce Prescriptions within standard healthcare practice through its federal and state policy working groups, grassroots working group, and steering committee leadership. Tufts' Food is Medicine research has included a focus on helping stakeholders, including health care providers and payers, build an economic case for these initiatives. Tufts has heard some of these stakeholders express concerns around inducement prohibitions and lack of guidance from government authorities.

As part of an interdisciplinary team of researchers and practitioners, CHLPI and Tufts developed an in-depth analysis of inducement prohibitions as a barrier to Food is Medicine and related recommendations. The article has been accepted by and is in press at the *Journal of Law, Medicine, and Ethics*; a pre-publication copy accompanies this letter.

We would like to share three core findings of this work:

1. **The existing options for compliance are unduly limiting and may exacerbate inequity.**

Health care organizations determined to implement food and nutrition supports have three primary options: (1) limit programming to activities that do not involve providing food to patients either directly (e.g., a food box) or indirectly (e.g., a food voucher) but instead focus on less integrated programming such as patient education about community resources; (2) invest time and resources into a narrowly-tailored, limited program compliant with the conditions of a safe harbor or exception; or (3) bear the risk of noncompliance with the law.

Each pathway poses challenges to truly addressing food insecurity and poor nutrition. Existing guidance on the application of safe harbors and exceptions to Food is Medicine programming is explored in detail in our article at Table 2. We urge OIG to note the limitations imposed, for example, by the 2020 patient engagement and support safe harbor monetary cap for items and services. An annual limit of $500 severely restricts the operation of highly impactful medically-tailored meals interventions under this safe harbor; such a program can cost about $350 per patient per month to operate.

Further, because of limited flexibility or ability to streamline interventions within the current framework of safe harbors and exceptions, the cost to organizations likely grows when providers want to set up different programs to respond to varied patient needs (e.g., food programs to improve health outcomes for multiple chronic illness patient groups and programs to address multiple health-related social needs for a particular patient population). This outlay creates barriers to entry for health care organizations. It penalizes organizations—and their patients—with fewer financial and human resources to dedicate to innovation, competing priorities, and less flexibility to take on even a specter of legal risk.

2. **Resolving concerns around inducement prohibitions will continue to be important despite growing coverage for food and nutrition supports in Medicare and Medicaid.**

Regulatory reforms and state-level Medicaid demonstrations are opening pathways to formal coverage of food interventions. Increasingly as a result, food and nutrition supports are becoming covered benefits in Medicare and Medicaid. However, these pathways are still severely limited by geography, managed care enrollment, and experimentation with hyper-targeted populations. Many health care organizations will continue to serve patients who could benefit from food and/or nutrition supports but are not able to access them as insurance benefits. In this environment, it remains critical to resolve concerns regarding inducement prohibitions to provide clear parameters to health care organizations as they strive to fill gaps in access.

3. **HHS OIG could have a significant impact on equitable access to Food is Medicine programming by creating new safe harbors and by disseminating information resources.**

While fraud and abuse laws play an important role in safeguarding federal health care program resources, there is an increasing tension between the urgency to address nutritional and social needs as a health intervention and the classification of certain goods and services as inducements under current law.

We encourage HHS OIG to consider rulemaking for the development of a safe harbor that would enable under one umbrella a broad range of Food is Medicine interventions to be delivered without violating AKS or CMPL. Additionally, or in the alternative, HHS OIG has several tools at its disposal, such as policy bulletins, FAQs, and toolkits, to assist various segments of the health care industry navigate and adhere to the law. Robust agency engagement on how to structure effective, flexible, compliant programs within existing constraints would help more health care providers pursue food and nutrition supports for their patients.

We urge HHS OIG to play its part in propelling Food is Medicine programs through enabling both meaningful *and* legally-compliant interventions. We would welcome the opportunity to work with you on this issue, to elaborate on our comments in this letter, and to bring additional resources to life. Please feel free to contact Rachel Landauer (rlandauer@law.harvard.edu), Kathryn Garfield (kgarfield@law.harvard.edu), or Dean Dariush Mozaffarian (dariush.mozaffarian@tufts.edu).

Sincerely,

Center for Health Law and Policy Innovation of Harvard Law School

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

CC:
Secretary Xavier Becerra
Robert K. DeConti