Mitigating Fraud and Abuse Law as a Barrier to **Food is Medicine**

A Path Forward

Background

Food is Medicine (FIM) programs target poor health outcomes associated with food and nutritional insecurity by deploying medically appropriate foods in a variety of ways to prevent, manage, or treat diet-related disease. While increasingly integrated into health care, federal fraud and abuse law has a significant chilling effect on the ability of providers to offer these services and supports. Concern about deploying FIM programs takes into account two related legal considerations:

1. The provision of food supports to Medicare or Medicaid patients, directly or through a vendor, at no cost to the patient may implicate the federal anti-kickback statute and civil monetary penalties law provision against beneficiary inducements; and
2. Existing safe harbors—i.e., business and payment arrangements that, although they potentially implicate the anti-kickback statute and civil monetary penalties law, are not treated as offenses—are insufficient to deploy FIM interventions in ways that have demonstrated therapeutic effect.[1]

A specific safe harbor is necessary to enable health care organizations that want to address the intersection of hunger, nutrition, and health to do so with maximal impact for their target patient population.[2]

Part I of this resource offers consensus-based model language for a FIM safe harbor. **Part II** highlights key arguments in support of adopting this safe harbor.

> "While increasingly integrated into health care, federal fraud and abuse law has a significant chilling effect on the ability of providers to offer Food is Medicine (FIM) services and supports."

1. For example, in order to avoid implicating the civil monetary penalties law provision against beneficiary inducements, health care organizations may limit the dollar value of food supports to $75 per patient, per year. This is too low for most interventions. Per Massachusetts Medicaid program's health-related social needs supplemental services fee schedule, "medically-tailored, home delivered meals" may be reimbursed up to $390.18 per week (maximum fee per unit x maximum units per week). "Nutritionally appropriate food prescriptions and vouchers" may be reimbursed up to $152.50 per month (maximum fee per unit x maximum units per month). Per North Carolina's Healthy Opportunities Pilots fee schedule, a "medically tailored home delivered meal" may be reimbursed up to $166.32 per week (maximum fee per unit x maximum units per week). A "fruit and vegetable prescription" may be reimbursed up to $248.43 per month.
2. There is precedent for this type of safe harbor. In 2016, for example, regulators established a safe harbor for local transportation services.

Part I. FIM Safe Harbor Model Language

Between September 2024 and April 2025, the Center for Health Law and Policy Innovation of Harvard Law School convened an advisory group to develop a model regulatory proposal.[3] Advisory group members represented health care organizations, nutrition organizations, and attorneys from across the country.[4] The following consensus-based language emerged from that initiative:

(1) As used in section 1128B of the Act, "remuneration" does not include the direct or indirect provision of food to an individual as part of a food is medicine program if all of the following conditions are met:

(i) The food is medicine program is conducted pursuant to a written protocol specifying:

(a) the goal of the program;

(b) description of the intervention (e.g., pantry stocking, nutrition prescriptions, medically-tailored groceries, medically-tailored meals);

(c) duration of the intervention (e.g., one-off, as necessary, six-months with possibility to renew);

(d) the criteria used to identify eligible participants;

(e) whether food support is provided to participants directly or indirectly; and

(f) any other limitations that will apply to the program; and

(ii) The food is medicine program does not result in medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program.

(2) For purposes of this safe harbor, a food is medicine program means any program that promotes health and/or healing by providing nutritious food. The direct provision of food means that the eligible entity itself provides food to participants. The indirect provision of food means that the eligible entity provides food to participants through one or more third parties. Food support refers to in-kind support; food support does not include cash or cash equivalents.

An important note on cash and cash equivalents: Not all prepaid cards, gift cards, or vouchers fit into this category.

The Office of Inspector General (OIG) distinguishes cash and cash equivalents from certain forms of prepaid cards, gift cards, and vouchers that are considered in-kind supports:[5]

- Cash refers to "monetary payments in the form of currency" and includes monetary payments transmitted electronically.
- Cash equivalents include "items convertible to cash (such as a check) or items that can be used like cash, such as a general-purpose prepaid card such as a Visa or Mastercard gift card. Gift cards offered by large retailers or online vendors that sell a wide variety of items (e.g., big-box stores) could easily be diverted from their intended purpose or converted to cash. Consequently, OIG considers such gift cards to be cash equivalents."
- In-kind supports include: (1) "gift card[s] to a big-box store for a particular item or select categories of items, such as a gift card to a big-box store that can, by its express terms, be used only to purchase fresh food items (e.g., produce)" and (2) "vouchers for a particular item or service (e.g., a meal or taxi ride) . . . ."

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3. This project was led by Rachel Landauer, Center for Health Law and Policy Innovation of Harvard Law School, with support from Reo Hayashizaki, Harvard Law School Health Law and Policy Clinic student, and Katie Garfield, Center for Health Law and Policy Innovation of Harvard Law School. The project was made possible through the generous support of the Kaiser Permanente National Community Benefit Fund at the East Bay Community Foundation.
4. Advisory group members included: Adam Falcone, Feldesman Leifer LLP; Alison LeBlanc; Adam Shyevitch, Chief Program Officer, About Fresh; Jean Terranova, JD, Senior Director of Policy and Research, Community Servings; Kim Corbin, Corbin Strategies; and others.
5. *See, e.g.*, US Department of Health and Human Services, Office of Inspector General, FAQs–General Questions Regarding Certain Fraud and Abuse Authorities, available at https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.

Part II. FIM Safe Harbor Rationale

The model safe harbor above is in alignment with the key criteria that federal regulators consider when reviewing a new safe harbor:[6]

1. **The model safe harbor will positively impact access to health care services, quality of health care services, and the ability of health care facilities to provide services in medically underserved areas / to medically underserved populations.** FIM programs eliminate food access-related barriers to compliance with treatment regimens,[7] support management of diet-related illness,[8] improve a health care organization's ability to engage patients and promote access to care,[9] and are increasingly recognized as part of a value-based care program.[10] The provision of FIM services and supports is especially relevant to care quality in light of expanding mandates for health care organizations to screen patients for food insecurity.[11]
2. **The model safe harbor explicitly prohibits a program that results in overutilization of health care services or increasing cost to Federal health care programs based on such overutilization.** Requirements for documentation of program design, related protocols, and limitations are additional sources of oversight that minimize the risk of fraud or abuse.
3. **FIM programs have the potential to decrease costs to Federal health care programs by addressing the significant burden of diet-related illness.** For example, studies have shown that the medically-tailored meal intervention can lead to reductions in emergency department visits (70%), inpatient hospital admissions (52%), admissions to skilled nursing facilities (72%), and net health care costs (16%).[12]
4. **The model safe harbor should not decrease patient freedom of choice or competition among health care providers.** Regulators are concerned about the improper steering of patients; however, as established at (1), above, health care providers leveraging FIM are offering an opportunity for eligible patients to receive higher quality care.

FIM Safe Harbor Criteria

FIM safe harbor:

- ✔ Boosts access to Food Is Medicine (FIM)
- ✔ Positively impacts heath care quality
- ✔ Reasonable reporting requirements prevent overutilization
- ✔ Does not limit patient freedoms

Increasing access to FIM:

- ✔ Eliminates food access-related barriers
- ✔ Improves treatment of diet-related diseases
- ✔ Improves patient care & engagement
- ✔ May significantly decrease hospital & ER visits
- ✔ May significantly decrease health costs

Conclusion

While the integration of food and nutrition supports into health care continues to gain momentum, the response by health care organizations will be lacking until regulators address federal fraud and abuse law as a barrier. With model language at the ready, advocates are prepared for and eagerly await reform.

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6. Regulators will consider various factors in reviewing proposals for additional safe harbors, including the extent to which the proposals may result in an increase or decrease in: access to health care services; the quality of health care services; patient freedom of choice among health care providers; competition among health care providers; the cost to Federal health care programs; the potential overutilization of health care services; and the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations. *See* 42 U.S.C. § 1320a–7d(a)(2).
7. *See e.g.*, Francesca Gany et al., Food to Overcome Outcomes Disparities: A Randomized Controlled Trial of Food Insecurity Interventions to Improve Cancer Outcomes, 40 (31) Journal of Clinical Oncology 3603 (2022), https://doi.org/10.1200/JCO.21.02400.
8. *See e.g.*, Hilary K. Seligman et al., A Pilot Food Bank Intervention Featuring Diabetes-Appropriate Food Improved Glycemic Control Among Clients In Three States, 34(11) Health Affairs 1956 (2015), https://doi.org/10.1377/hlthaff.2015.0641.
9. Jessica Macinkevage et al., Washington State's Fruit and Vegetable Prescription Program: Improving Affordability of Healthy Foods for Low-Income Patients, 18(16) Preventing Chronic Disease E:91 (2019), https://doi.org/10.5888/pcd16.180617.
10. *See, e.g.*, Office of the Assistant Secretary for Health, Bright Spots Profile: Using a Value-based Care Model to Implement Food is Medicine Interventions, available at https://odphp.health.gov/foodismedicine/promising-practices-and-tools/bright-spots/using-value-based-care-model-implement-food-medicine-interventions.
11. Research suggests that screening for health-related social needs, without being able to offer patients responsive services and supports, has negative impacts on both providers and patients. *See e.g.*, Jason J. Ashe et al., Screening for Health-Related Social Needs and Collaboration With External Partners Among US Hospitals, 6(8) JAMA Network Open (2023), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808708.
12. Seth Berkowitz et al., Association Between Receipt of a Medically Tailored Meal Program and Health Care Use, 179 JAMA Intern. Med. 786 (2019),https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2730768; Seth Berkowitz et al., Meal Delivery Programs Reduce Use of Costly Health Care in Dually Eligible Medicare and Medicaid Beneficiaries, 37(4) Health Affairs 535 (2018), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0999.