Is that Hospital Food Pantry an Illegal Patient Inducement? Analysis of Health Care Fraud Laws as Barriers to Food and Nutrition Security Interventions

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Abstract: The complex regulatory framework governing the U.S. health care system can be an obstacle to programming that address health-related social needs. In particular, health care fraud and abuse law is a pernicious barrier as health care organizations may minimize or forego programming altogether out of real and perceived concern for compliance. And because health care organizations have varying resources to navigate and resolve compliance concerns, as well as different levels of risk tolerance, fears related to the legal landscape may further entrench inequities in access to meaningful programs that improve health outcomes. This article uses food and nutrition programming as a case study to explore the complexities presented by this area of law and to highlight pathways forward.

On September 3, 2020, during the second wave of the COVID-19 pandemic in the United States, the U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) responded to a question from a federally qualified health center (FQHC): would it be a violation of federal health care fraud and abuse law to provide gift cards to certain Medicare and Medicaid beneficiaries?[1] The FQHC had received a grant designated for emergency assistance and wanted to help patients address acute health-related social needs such as food and nutrition insecurity, housing instability, technology access issues, and barriers to transportation. Recognizing that safety net health care providers like FQHCs are well-positioned to provide such assistance during the pandemic, HHS OIG answered that the proposal — subject to a lengthy list of conditions — could go forward.

The FQHC was seeking clarity on a complex area of health care law concerned with the provision of free or discounted items and services to Medicare and Medicaid beneficiaries. The underlying rationale is that such arrangements might distort beneficiary decision-making. In other words, the opportunity to receive a gift card may influence someone's choice of health care provider or even cause someone to seek additional health care services that are not medically necessary. This is known as "inducement," and the consequences for a misstep in this area of law can be significant. As recently as 2021, a mail-order diabetic testing supplier paid $160 million dollars to settle allegations including that the company provided free glucometers to Medicare beneficiaries to induce them to order testing supplies from the company.[2]

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Questions about how the law treats items and services that address unmet health-related social needs are particularly pressing in light of rapidly increasing recognition of the fundamental importance of addressing such needs, including interventions to improve food security (the ready availability of nutritionally adequate and safe foods, and assured ability to acquire acceptable foods in socially acceptable ways) and nutrition security (consistent and equitable access to healthy, safe, affordable foods essential to optimal health and well-being).[3] Health care organizations are increasingly operating on-site food-related interventions, partnering with community food programs, or providing "prescriptions," vouchers, or rebates to improve access to produce, groceries, and medically tailored meals at reduced or no cost to patients. This is driven by several related forces: an understanding of the intimate association between food insecurity, poor diet quality, chronic illness, and health care costs — the evidence linking both food security and good nutrition with better health outcomes and reduced health care utilization continues to grow[4]; the links between these issues and racial inequities[5]; and high rates of food insecurity and poor nutrition in the U.S.[6]

This article uses food and nutrition programming as a case study to explore the complexities presented by this area of law. We begin by contextualizing why health care entities are implementing food and nutrition programs for patients. Then we discuss the evolving policy landscape and the ongoing pressure for the integration of social needs services and supports at the provider level. We analyze the health care fraud and abuse legal framework as it applies to innovative programming. This discussion focuses on identifying specific features of the legal framework that interact with, impact, and ultimately constrain the ability of health care systems to care for patients. Our concluding section addresses implications for policy and practice, highlighting opportunities for regulatory and institutional policy to better reflect the importance and reality of responding to food, nutrition, and other health-related priorities in health care systems.

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Overview of Relevant Law

The complexity of the existing legal framework is a large, pernicious barrier to the integration of health care-related programs providing food, nutrition, transportation, and housing supports. Health care organizations may limit or avoid these health-related programs due to real or perceived concerns about compliance with the federal Anti-Kickback Statute (AKS) and the beneficiary inducements prohibition of the Civil Monetary Penalties Law (CMPL) (Box). In the example above, the FQHC proposed carefully and narrowly defining who would be eligible to receive a gift card (people who documented financial need relating to COVID-19), the amount of assistance people would be eligible to receive (a one-time transfer of $100-$200, depending on family size), and various operational parameters (such as a commitment that

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the FQHC would not advertise the program) in pursuit of approval by HHS OIG.[7] Together, the legal concerns and resulting tightly limited parameters of such programs may significantly reduce their implementation, scalability, and impact

The Role of Food and Nutrition Interventions in Clinical Care

Achieving or maintaining optimal well-being requires a focus on drivers of poor health, among which food insecurity and nutrition is at the top.[9] Annually, more than 300,000 American deaths from cardiovascular disease and diabetes are attributable to suboptimal diet[10] and diet-related illness including diabetes, cardiovascular diseases, chronic kidney disease, cancers, and obesity are leading risks for COVID-19 hospitalizations and deaths.[11] In one analysis, diet-related diseases and food insecurity together contributed to more than $1 trillion in annual health care spending.[12] Food insecurity is associated with increased hospitalizations and emergency department visits and higher health care spending;[13] people who are food insecure are more likely to be among those incurring the top 10%, and even 2%, of health care expenditures.[14] National metrics for nutrition insecurity — a complementary concept which additionally highlights the quality of food[15] — remain to be defined, but based on validated dietary scores, 32% and 65% of foods consumed among American adults from grocery stores and restaurants, respectively, are of poor nutritional quality; and 45% and 80% among American children.[16]

Food insecurity, poor nutrition, and diet-related diseases are each more prevalent among marginalized subgroups, including individuals with less education, lower income, rural residence, and racialized groups. For example, during the first year of the COVID-19 pandemic, compared with White, non-Hispanic households, household food insecurity was more than 2-fold higher among Hispanic households, and 3-fold higher among Black, non-Hispanic households.[17] Similar large disparities exist for good nutrition and rates of diet-related chronic diseases.

Specific "food is medicine" interventions offer promising health care mechanisms to improve food security, nutrition, and health outcomes.[18] These include produce prescriptions, which provide free or discounted produce at retail or farmers markets using vouchers or electronic cards, and medically tailored meals, which provide fully prepared, often home delivered meals for patients with advanced disease. Both interventions are associated with improved health outcomes,[19] and medically tailored meals have documented reductions in health care utilization and total costs.[20]

Box

Overview of Federal Law

- The Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7(b), generally prohibits knowingly and willfully offering, paying, soliciting, or receiving anything of value with the intent to induce or reward referrals for items/services payable under a federal health care program.
- The Civil Monetary Penalties Law (CMPL) Prohibition on Beneficiary Inducements, 42 U.S.C. § 1320a-7a, generally prohibits offering free or discounted items or services to a federal health care program beneficiary that are likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier. Items and services of "nominal value" — currently interpreted as something with a retail value of no more than $15 per item or $75 in the aggregate per patient per year — are below the threshold necessary to trigger the CMPL.[8]
- Recognizing that some arrangements that might violate the AKS or CMPL are ultimately beneficial for patients and the health care system, the government has created safe harbor regulations that exempt certain arrangements from AKS and CMPL liability and additional exceptions to the CMPL inducements prohibition. For example, there is a safe harbor that protects payments to induce a health care provider to relocate their practice to an underserved area.
- Programs that fall outside of a safe harbor or exception do not automatically violate the law. Those analyses are case specific, meaning that each arrangement is individually evaluated.

The growing interest in such food programs is evidenced by White House commitments to integrating nutrition and health in the second-ever White House Conference on Hunger, Nutrition, and Health and the National Strategy released in connection therewith,[21] Medicaid pilots in Massachusetts, North Carolina, and (more recently) several additional states that allow payments for produce prescriptions and medically tailored meals,[21] and by large private entities such as Kaiser Permanente which have committed to treating patient food insecurity and expanding effective nutrition programs.[23] 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 cur-

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rent law. These tensions may limit the expansion of nutrition programs that could improve patient health outcomes and health equity.

Disparate Coverage of Health-Related Social Need Supports as Insurance Benefits: The Evolving Policy Landscape

Confusion over whether a nutritional or health-related social need support is an illegal inducement effectively disappears if the support is a covered insurance benefit. An item or service lawfully delivered in accordance with an insurance benefit is not considered free or discounted in violation of AKS or CMPL, even if the patient bears no out-of-pocket cost. Increasingly — though unevenly — health-related social need supports are becoming part of covered benefits. With respect to food, regulatory reforms and state-level Medicaid demonstrations are opening pathways to formal coverage of food interventions. (*See* Table 1.) However, these pathways are still severely limited by geography, managed care enrollment, and experimentation with hyper-targeted populations, and thus most health care organizations serve patients who could benefit from food and/or nutrition supports but are not able to access them as insurance benefits.[24]

Table 1

Current Opportunities to Include Food and Nutrition Supports in Public Insurance Programs

Public Program	Opportunity	Description
Medicare	Medicare Advantage (Medicare Part C) Supplemental Benefits • General Supplemental Benefits[a] • Special Supplemental Benefits for the Chronically Ill (SSBCI)[b]	Historically, the Centers for Medicare and Medicaid Services (CMS) has allowed coverage for meals as a Medicare Advantage supplemental benefit under certain limited circumstances. SSBCI, first tested in the 2020 plan year, permits Medicare Advantage Organizations (MAOs) to offer meals, produce, and other food supports to enrollees with a chronic illness. Benefits must have a "reasonable expectation of improving and maintaining the health or overall function of the chronically ill enrollee."
Medicare	Medicare Advantage (Medicare Part C) Value-Based Insurance Design Model (VBID)[c]	The VBID Model is a demonstration project operated by the Center for Medicare and Medicaid Innovation. This model creates additional flexibility compared to SSBCI because it enables beneficiaries to receive benefits based on socioeconomic status as well as chronic conditions.
Medicaid	State Plan Amendments and Waiver Authorities • 1115 • 1915(c) • 1915(i) • 1915(k)	Many state Medicaid programs provide meals as part of their home and community-based services to individuals who would otherwise require an institutional level of care. This is made possible by the Medicaid Home and Community-Based Services authorities (i.e., Sections 1915(c), 1915(i), and 1915(k)). Increasingly, states are using Medicaid Demonstration Waivers (i.e., Section 1115 Waivers) to pay for meals, healthy food vouchers, and other nutrition-relevant services.
Medicaid	Managed Care Flexibilities[d] • In Lieu of Services • Value-Added Services • Quality Improvement Activities	In addition to state options, Medicaid managed care organizations have the flexibility to provide more benefits than those dictated under a state plan through a series of regulatory provisions enabling "in lieu of" services, value-added services, and quality improvement services.

[a] Ctrs. for Medicare & Medicaid Servs., *Medicare Managed Care Manual Chapter 4 – Benefits and Beneficiary Protections* (last issued April 2016), *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf.
[b] 42 C.F.R. § 422.102.
[c] Ctrs. for Medicare & Medicaid Servs., *Value-Based Insurance Design Model Request for Applications for CY 2022* (2021), *available at* https://innovation.cms.gov/media/document/cy-2022-vbid-rfa-final.
[d] 42 C.F.R. § 438.3(e).

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Food and Nutrition Supports Through an Inducements Lens

Where food and nutrition support is *not* a covered benefit, the legality of it being furnished by a health care organization grows murkier. The standard inducements inquiry proceeds as follows: First, is something being transferred to the patient for free or at a discounted rate? If not, the arrangement may proceed without further concern. Second, if something of value is being transferred for less than its market value, does the arrangement fit within an AKS safe harbor or, for CMPL purposes, an exception? If so, the arrangement may again proceed without further concern. Finally, if there is no safe harbor or exception that obviously applies, attention turns to whether, based on a review of specific facts and circumstances, the arrangement is a violation of the AKS and/or CMPL.

As applied, 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); (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 of these options, explored below, pose challenges to meaningfully addressing food and nutrition insecurity. Further, because there is no "one size fits all" approach, organizational investment 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.

1. Organizations can avoid exposure to the law altogether by implementing less integrated programming and maintaining historical siloes between clinical care and social services.

Some forms of food-related supports offered by a health care organization do not involve providing something to patients for free or at a discounted rate. Examples including educating patients on community food programs and providing enrollment assistance in government nutrition programs such as the Special Supplemental Nutrition Program for Women, Infants, and Children.[25]

This approach is sufficient for some patients and in some communities but not all. There are benefits to more integrated programming such as a hospital-based food pantry in which patients can access multiple services in one place.[26] Government nutrition benefits are relatively modest and may be inadequate to meet a person's need, warranting supplemental interventions.[27] Moreover, while community-based organizations are valuable partners in addressing health-related social needs, programs limited to screening and referral direct financial and other burdens of service delivery to be borne primarily — or entirely — by the community-based organization.[28]

2. Organizations can develop a limited program compliant with the conditions of a safe harbor or exception.

There is no single, comprehensive safe harbor or exception to enable the deployment of food and nutrition interventions. Instead, health care organizations can develop initiatives to comply with safe harbors or exceptions describing broader, yet related, goals (e.g., helping patients with financial need to access supports that improve health status). Two safe harbors and three exceptions are particularly relevant: the safe harbor for CMS-sponsored models; the patient engagement and support safe harbor; the financial need-based exception; the preventive care exception; and the exception protecting items/services that promote access to care and pose a low risk of harm. A brief overview of each of these provisions is provided in Table 2, which discusses the type of arrangements broadly protected by each exception, some of the key requirements that must be satisfied in order to rely on the provision for immunity, and agency guidance regarding application to food-related supports in particular.

The majority of these compliance avenues are relatively new with four of the six created within the past six years. And while their emergence signals that federal regulators are interested in leveraging social supports to improve health outcomes and reduce health care costs, policy reform has been incremental.

In 2020 HHS OIG enacted a new patient engagement and support safe harbor.[29] The new rule protects certain supports provided to patients to improve care quality, health outcomes, and efficiency as part of a value-based undertaking. The scope of the safe harbor explicitly includes items, goods, and services to address health-related social needs. Hospital-run food pantries, food vouchers, grocery and meal deliv-

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Table 2
Safe Harbors and Exceptions Applicable to Furnishing Food-Related Supports

Scope of immunity	Permissible goals	Permissible form(s) of support	Eligible patients	Monetary limits
Patient Engagement and Support Safe Harbor (42 C.F.R. § 1001.952(hh))				
Anti-Kickback Statute (AKS) and beneficiary inducements prohibition of the Civil Monetary Penalties Law (CMPL)	Includes prevention or management of a condition as recommended by patient's health care provider	- In-kind items, goods, or services (e.g., on-site food pantries, food vouchers) are permissible - *Cash or cash equivalents (e.g., general purpose gift cards) are impermissible* - Health care providers are permitted to contract with CBOs to furnish supports to patients	Patients in a "target population" (e.g., patients with chronic diabetes or another specific illness)	Aggregate retail value of tools and supports provided to a patient cannot exceed $570 in 2023 (cap is adjusted annually for inflation)
Safe Harbor for Centers for Medicare and Medicaid Services (CMS) Model Arrangements (42 C.F.R. § 1001.952(ii))				
AKS and CMPL	Allows health care organizations participating in a model tested by the CMS Innovation Center (CMS-sponsored model) to provide free or discounted items to patients to advance a goal of the CMS-sponsored model	Depends on the CMS-sponsored model Notes: • Meal program vouchers to address malnutrition is an allowable incentive by Medicare Shared Savings Program Accountable Care Organizations[a] • Per guidance, the provision of food vouchers to a Medicare Diabetes Prevention Program participant living in a "food desert" is an allowable — and often effective — tool because it supports Type 2 diabetes risk reduction[b] • Per guidance, giving "multiple free meals or meal replacement services … over a substantial portion" of a person's participation in the Medicare Diabetes Prevention Program is not permitted[c]	Depends on the CMS-sponsored model	Depends on the CMS-sponsored model
Financial Need-Based Exception (42 C.F.R. § 1003.110(8))				
CMPL	Improving access to supports that have a reasonable connection to a patient's medical care	- Items, goods, and services - *Cash or cash equivalents are impermissible*	- Patients with "financial need" as determined through a good faith and individualized assessment - Providers are not required to use any specific basis for determining need but a uniformly applied policy is required[d]	The cost of the intervention cannot be "too large" compared to value of the service[d] Note: Guidance states that providing meal deliveries for a "limited period of time" after a patient is discharged

(Continued)

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Table 2 (continued)

Scope of immunity	Permissible goals	Permissible form(s) of support	Eligible patients	Monetary limits
			- Enrollment in Medicaid may be used for the assessment[d] - A food insecurity screening tool (e.g., Hunger Vital Sign™) may be permissible for determining need where the provider can be reasonably comfortable accepting only a patient's statement of need (e.g., the provider is located in a low-income area and generally serves low-income patients)[d]	following a debilitating procedure may be reasonable but that paying for a subscription to a "long-term" meal delivery service for a patient with diabetes is not reasonable[d]
Preventive Care Exception (42 C.F.R. § 1003.110(4))				
CMPL	Incentivizing a patient to access an eligible service	Incentives do not need to be related to care	Patients in need of certain clinical preventive services including prenatal services, well-baby visits	The cost of the incentive cannot be "too large" compared to the value of the service
Promotes Access to Care Exception (42 C.F.R. § 1003.110)				
CMPL	Supporting a patient's ability to obtain medically necessary care	- Items/services that improve access to care while posing a low risk of harm to patients and health care programs - *Cash or cash equivalents are impermissible* Notes: • In one advisory opinion, regulators approved an arrangement to provide lodging and free meals to low-income patients from rural and/or medically underserved areas who have an early morning appointment or need follow-up care[e] • Per guidance, food vouchers/meal services to "promote access to healthy living" do not meet the requirements of this exception and are thus not protected under the exception[d]	Patients who face socioeconomic, geographic, or other barriers to accessing care	No specific limit imposed

[a] Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017, 83 Fed. Reg. 67816 (Dec. 31, 2018); 42 C.F.R. § 425.304.

[b] Medicare Learning Network, Transcript, *Medicare Diabetes Prevention Program: Supplier Enrollment Call* (2018), *available at* https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2018-06- 20-MDPP-Transcript.pdf.

[c] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program, 82 Fed. Reg. 53331 (Nov. 15, 2017).

[d] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368 (Dec. 7, 2016).

[e] HHS OIG Advisory Opinion No. 17-01 (2017), *at* https://www.oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-01.pdf.

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ery services, and nutrition education are among the examples of supports envisioned.

While the new rules create opportunity to expand food and nutrition programs, HHS OIG attached an array of administrative burdens and conditions that curtail impact. Most significantly, the aggregate value of tools and supports provided by an organization to any single patient is limited by an annual monetary cap. The initial cap was $500 and is adjusted each calendar year for inflation; for 2023, the cap is $570. This cap meaningfully limits the types and quality of services available. For example, research shows that medically tailored meals can significantly reduce net health care utilization and total health care costs for high-risk patients with chronic disease; however, some analyses (unadjusted for inflation) cost programs at about $350 per patient per month to operate.[30] The annual monetary cap may also stand in the way of creating comprehensive wraparound services and instead pits areas of patient support such as nutrition, housing, and medication management against one another. Critically, this tension may lead to care decisions based on gross cost rather than on patient needs, intervention efficacy, and cost-effectiveness.

3. Organizations implement programming that bears legal risk.

In addition to time and resources, proceeding to this third option requires greater confidence in an increasingly complex legal argument.

HHS OIG guidance, including preamble commentary to regulations and legal advisory opinions, indicate an openness to appropriately structured programming to address health-related social needs.[31] This body of

Table 3

Common AKS/CMPL Safeguards

Eligibility for assistance is not tied to business	The Department of Health and Human Services Office of Inspector General (HHS OIG) is wary of arrangements that base eligibility on a person's past or anticipated use of a provider's health care services. A major red flag is the conditioning of assistance on a person agreeing to become or to continue as a patient.[a]
Arrangement involves provision of items and/or services vs. cash and cash-equivalents	HHS OIG is more wary of the provision of cash than it is of non-monetary assistance.[b] The OIG views vouchers for a specific type of support (e.g., a food voucher) as an acceptable approach to structuring an in-kind arrangement.[b] A general purpose debit card, on the other hand, is not.
Arrangement is not advertised	HHS OIG generally prohibits advertising assistance programs because of concerns that it will steer or coerce people towards other, reimbursable services. Although "whether a particular means of communication constitutes an advertisement or solicitation will depend on the facts and circumstances," [c] HHS OIG recognizes that providing basic information relating to available supports does not violate marketing prohibitions.[b] HHS OIG explains that it is therefore acceptable for a hospital food pantry to post its hours of operation. Additionally, screening patients for a need (e.g., food insecurity) opens the door to informing eligible patients about related supports available to them without advertising the program to the general patient population.
Arrangement involves relatively modest assistance	HHS OIG is more wary of the provision of luxury items or services (such as air transportation) than it is more modest forms (such as ground transportation).[c]
Arrangement is supported by written policies and documentation	Important matters to document may include the intent of the program, safeguards built into the program and how they are operationalized, and processes to monitor adherence to program policies.

[a] HHS OIG, *Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries* (2002), *available at* https://oig.hhs.gov/documents/special-advisory-bulletins/886/SABGiftsandInducements.pdf.
[b] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducement, 85 Fed. Reg. 77684 (Dec. 2, 2020).
[c] Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368 (Dec. 7, 2016).

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sub-regulatory policy arguably advances several "safeguards" — arrangements that enforcers highlight as helping to lower the risk of fraud and abuse in the absence of a perfect safe harbor or exception fit. (*See* Table 3.) However, only a small fraction of guidance wrestles with arrangements involving assistance for patient social needs. Of the 20 advisory opinions issued in 2021, for example, there was only one on the topic.[32]

The more innovative the programming the less likely it is that some version of it has been explicitly considered. Rather than "Arrangement A is explicitly permitted, so we shall do A", the analysis becomes trickier, for example, "Arrangements A, B, and C are permitted, and based on a close reading of their core components and safeguards encouraged in advisory opinions for Arrangements D and E, we are proceeding with Arrangement F." With each hypothetical food box distribution or medically tailored meal delivery compounding financial and criminal liability, health care organizations are likely to proceed only if they are confident in their own interpretation of government policy — regardless of any actual likelihood of an enforcement action being brought against them.

Conclusions

Interventions that directly address food and nutrition insecurity can be an important part of providing effective health care — especially for those enrolled in Medicare and Medicaid. An overabundance of caution about AKS and CMPL, on the part of policy makers and/or health care administrators, may leave these critical needs unaddressed. Furthermore, because health care organizations have varying resources to navigate and resolve complex compliance concerns, as well as different levels of risk tolerance, nutrition and other health-related social needs programs may be least available among less resourced, smaller, and more rural providers. Thus, fears related to the legal landscape may exacerbate inequities in access to innovative programs that improve health outcomes.

Integrating interventions that address nutrition and unmet health-related social needs as crucial covered benefits would have the largest and most direct positive impact. The federal government can then best leverage its investments and programming to harmonize health care with the centrality, magnitude, and range of patients' social needs.

In the absence of covered benefits, institutions and policy makers alike have a role to play in advancing food and nutrition security within the constraints of current health care fraud and abuse law.

For example, HHS OIG has several tools at its disposal, such as advisory opinions, policy bulletins, FAQs, and toolkits, to assist various segments of the health care industry navigate and adhere to the law. Additional agency engagement on how to structure compliant programs would help more health care providers to pursue food, nutrition, and other supports for their patients. Especially in the wake of the National Strategy on Hunger, Nutrition, and Health, which calls for a whole-of-society response, HHS OIG has a central role to play propelling interventions forward.

For health care organizations, applying a solutions-oriented, practical examination to legal risk will better enable health care entities to realize the full benefits of innovations that address food and nutrition security. This should include recognition that, to date, HHS OIG has indicated an openness to many forms of support and that the National Strategy calls upon regulators to unlock — not block — programming. Such strategic engagement with fraud and abuse law is a basic next step to advance food and nutrition insecurity interventions in health care, with potential to improve quality of care, well-being, and health equity among millions of Americans living in an era of compounding epidemics. The alternative is to further entrench inequity, surrender cost-effective opportunities to improve patient outcomes, and risk lagging behind peer organizations.

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