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Feeding Better Outcomes: The OIG's Compliance Roadmap for Food-As-Medicine Programs

The OIG's Message: Food Can Be Medicine—*But Still Create Legal Risk*

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By: Michael A. Dowell

Food-as-medicine programs are increasingly being considered as clinical and population health tools for patients with diet-sensitive chronic conditions. For health centers, providers, hospitals, Programs of All-Inclusive Care for the Elderly (PACE) organizations, and managed-care entities, the strategic objective is straightforward: **make prescribed nutrition support available when food insecurity would otherwise undermine the care plan.**

OIG Advisory Opinion No. 26-16 (AO 26-16), issued July 9, 2026, offers an important, but limited, roadmap for doing so. In the precise arrangement presented, the OIG concluded that it would not impose administrative sanctions under the federal Anti-Kickback Statute (AKS) or the beneficiary-inducement Civil Monetary Penalties Law (CMP), even though the food benefit implicated both authorities.

The OIG's conclusion depended on a tightly controlled, clinically integrated model involving existing financially needy patients, objective health criteria, limited in-kind produce benefits, continued patient cost sharing, separate grant funding, and vendor redemption controls.

AO 26-16 is fact-specific and does not establish a generally applicable safe harbor. It nevertheless identifies design features that may help sponsors reduce fraud-and-abuse risk while improving chronic disease management, for health equity, community benefits, and value-based care.

Why Food-as-Medicine Programs Require Deliberate Design

Food-as-medicine reframes nutritious, condition-appropriate food as a clinical intervention, rather than charity. For patients with diabetes, hypertension, and other diet-sensitive conditions, medically appropriate food is a

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prerequisite for the care plan to work. But once food is tied to a diagnosis, a care plan, or billable services, it becomes remuneration under the AKS and CMP.

For low-income patients, therapeutic diets can compete with rent, medications, transportation, and utilities. A well-designed benefit can convert dietary guidance into a tangible resource and help close the gap between a care plan that exists on paper and one a patient can realistically follow. The compliance analysis, however, must be built into the model from the outset.

The Core Interventions Include:

- **Medically tailored meals**—Prepared meals aligned to diagnosis, allergies, and medication-related dietary needs.
- **Medically tailored groceries**—Condition-appropriate ingredients for patients able to cook at home.
- **Produce prescriptions**—Boxes, vouchers, or restricted cards for fruits and vegetables.
- **Healthy-food incentives**—Discounts or matching funds that lower the effective price of qualifying foods.

The Proposed Food For Medicine Program That the OIG Was Willing to Support

AO 26-16 is a fact-specific advisory opinion. Its practical value lies in the safeguards the OIG emphasized: limited duration and value, objective eligibility criteria, documented financial need, separate funding, clinical integration, preserved cost sharing, and meaningful vendor controls. These features should be viewed as an integrated risk-management framework, *not as a checklist that can be adopted mechanically.*

The requestor, a Section 330 federally qualified health center (FQHC) serving predominantly low-income patients, proposed a six-month pilot for 50 existing patients with financial needs. The OIG's analysis was based on the requestor's certified facts, including modest and time-limited in-kind benefits, grant funding, structured clinical integration, continued billing and cost sharing, and redemption controls. A sponsor proposing a materially different model should conduct a new, arrangement-specific analysis.

Who Received the Benefit?

- Existing patients ages 18–85 who met specified clinical and financial-need criteria. Insured status was not considered in participant selection.

What Did Patients Receive?

- One group received a $30 weekly box of fresh fruits and vegetables delivered to the home; another received a $20 weekly voucher redeemable only for healthy food at participating grocery stores and farmers' markets, administered by a third-party voucher company.

How Was Clinical Care Integrated?

- Participants received structured assessments (dietitian + behavioral health) with baseline, midpoint, and final metrics, individualized planning, labs, counseling, and physician oversight.

Who Qualified?

- Eligibility required an A1c of at least 7.0 within the prior three months or a blood pressure of at least 140/90 within the prior 12 months, willingness to participate in counseling, ability to participate without on-site translation, and established financial hardship.

How Was the Program Funded?

- The produce was supported by grant funding. Reimbursable clinical services continued to be billed under the center's fee schedule and sliding fee discount policy, including applicable contractual cost sharing. The center certified that, as additional funding becomes available, it will expand beyond 50 participants and add hyperlipidemia, obesity, and metabolic syndrome, chronic kidney disease, coronary artery disease, and congestive heart failure to the qualifying diagnoses.

The Safeguards That Made a Difference

Free produce furnished to a federal healthcare program beneficiary can constitute remuneration that may induce the beneficiary to obtain reimbursable services from the provider, including the assessment services associated with the program.

The OIG identified no applicable safe harbor and reiterated its longstanding concerns regarding free items and services furnished to beneficiaries. Furthermore, the OIG did not analyze whether its nominal-value exception or related guidance applied.

Given the recurring weekly benefit and total value over the six-month program period, sponsors should not assume that nominal-value principles provide a reliable basis for a clinically integrated food-benefit model. Instead, the opinion's analysis turned on the arrangement's overall safeguards and the resulting low risk of overutilization, increased program costs, and patient steering.

Low Risk of Overutilization and Added Cost

The program aligns with the center's Section 330 designation, and the produce is consistent with HRSA-approved additional services. The OIG highlighted that the remuneration is in-kind and non-cash, which reduces diversion risk, and that it is narrowly tailored to disease management. The OIG also credited the certification that the assessments establish baseline metrics and drive individualized care plans.

Low Risk of Patient Steering

The benefit was modest and time-limited in duration. Participants remain responsible for applicable cost-sharing on the assessment services, which the OIG said reduces the likelihood that the produce materially influences provider selection.

The voucher company's monitoring safeguards—summarized in the checklist below—also contributed to the OIG's support.

The Key Design Constraint: Clinical Integration Can Create Inducement Risk

The feature that makes a food-as-medicine initiative clinically meaningful—its connection to individualized assessment, care planning, counseling, and outcome monitoring—can also create beneficiary-inducement risk when those related services are reimbursable.

In AO 26-16, the OIG concluded that the financial-need exception did not apply because the food benefit was tied to reimbursable services. The remaining exception elements, including the absence of advertising, a reasonable connection to the patient's medical care, and a good-faith determination of financial need, did not resolve that threshold issue. See 42 C.F.R. § 1003.110; 42 U.S.C. § 1320a-7a(a)(5).

This creates a central design tension. Decoupling food support from clinical services may help meet the exception's "not tied to" requirement, but it can undermine the clinical-integration features that differentiate a food-as-medicine intervention from general food assistance. The OIG did not expand the exception; it instead declined to impose administrative sanctions based on the requestor's certified facts.

Program Rationale and Documentation

The OIG's conclusion rested on the requestor's certified facts rather than an independent review of clinical-outcomes literature. Sponsors should nevertheless document the evidence base, clinical rationale, target population, and expected outcomes for their own program.

The supporting record should explain why the selected benefit is reasonably tailored to the population's diet-sensitive conditions and how the organization will evaluate whether the intervention advances patient-care objectives rather than referral volume or utilization.

The OIG Design Checklist: Safeguards to Build Into the Program

Feature	Why it Matters
Keep the Benefit In-Kind	Use Restricted, In-Kind Benefits—Structure assistan groceries, restricted vouchers, or other non-cash be cards, and mechanisms that permit unrestricted sp risk.
Use Objective Clinical Criteria	Specific diagnoses with numeric thresholds, tied to
Document Financial Need	Established hardship criteria, applied before enroll
Ignore Insurance Status	Removes the inference that selection follows reimb
Existing Patients Only	Benefit does not recruit new patients
Limit Value and Duration	One box or voucher per week for six months
Keep Funding Separate	Segregate Funding Sources—Maintain clear accoun food benefit is not funded through clinical reimburs creates cross-subsidization concerns
Preserve Cost Sharing	Maintains patient responsibility; reduces steering ri
Keep Marketing Out of the Equation	Exclude the Benefit From Patient-Acquisition Efforts inducement to establish care, select a provider, enr services.
Maintain Redemption Controls	MOUs, receipt checks, site visits, and restricted SKU
Document Clinical Integration	Assessments establish baseline metrics and produc
Measure Clinical Outcomes	Baseline, midpoint, and final metrics tie the progra volume
Put Vendor Controls in Writing	Contract for Vendor Controls—Use written agreeme redemption limits, monitoring, reporting, privacy, a policies, and the separation of vendor compensatio

Feature	Why it Matters
Document Program Authority	Confirm the organization's authority to offer and fu requirements, managed-care benefit authority, con applicable plan or regulatory approvals.
Create an Audit-Ready Record	Retain clinical eligibility and financial-need determi participant records, vendor reports, cost-sharing do the legal analysis supporting the program structure

Which Organizations Have the Clearest Path?

AO 26-16 is most immediately relevant to health centers, but it also provides a practical planning framework for hospitals, health systems, PACE organizations, managed-care entities, Medicare Advantage organizations, D-SNPs, IPAs, physician organizations, MSOs, and vendors supporting food-benefit programs.

The legal pathway—and the diligence required—will differ materially based on the sponsor, funding source, reimbursement model, vendor relationships, and applicable state law.

Organization	Strategic Opportunity	Principal Legal and Operational Issue
FQHCs and Look-Alikes	Integrate nutrition support into chronic-disease management, health equity, and care-coordination initiatives	Scope-of-project alignment, sliding-fee compliance, preserved cost sharing, gra accounting, and clinical documentatio
Hospitals and Health Systems	Advance community-benefit, population-health, discharge-planning, and value-based-care objectives	Unlike FQHCs, hospitals may lack a Sec 330 framework and require an indepen AKS, CMP, billing, vendor, and state-law analysis
IPAs, Physician Organizations, and MSOs	Support risk-bearing providers and population-health initiatives	Physician referral, compensation, data-sharing, and vendor-arrangement risks

Organization	Strategic Opportunity	Principal Legal and Operational Issue
		be distinct from participant-benefit ana
PACE Organizations	Address participant nutrition needs as part of a coordinated, interdisciplinary care model	Enrollment-inducement risk, plan-of-ca documentation, marketing restrictions vendor referral arrangements
Medicare Advantage Organizations and D-SNPs	Offer food support through supplemental benefits and health equity strategies	Benefit authority, eligibility, uniformity, documents, member communications, marketing, and vendor oversight
California Medi-Cal Managed Care Organizations and Providers	Use Community Supports and related CalAIM pathways to address nutrition insecurity	Community Supports requirements, sta inducement rules, network and vendor contracting, and plan-provider respons allocation

What AO 26-16 Does—and Does Not—Provide

AO 26-16 provides a useful risk-assessment framework, but its protections are narrow and fact-specific. It addresses only the federal AKS and CMP authorities as applied to the requestor's certified arrangement. It does not resolve other legal, reimbursement, operational, or state-law issues that may apply to a proposed food-as-medicine program.

No Reliance for Third Parties

- The advisory opinion applies only to the requestor and the exact arrangement submitted to the OIG. Other organizations cannot rely on AO 26-16 for legal protection, even if their proposed programs appear

substantially similar.

- Sponsors should instead use the opinion to identify relevant risk factors, compare their facts with the certified arrangement, and document the reasons for any material departures.

No Stark Determination

- The OIG expressly reserved judgment regarding the physician self-referral law (Stark Law). Any program involving physician compensation or referral relationships connected to nutrition services, therefore, requires a separate Stark Law analysis.

No False Claims Act Determination

- The opinion does not address potential False Claims Act liability or related issues involving billing, claims submission, or cost reporting. Those issues require separate review.

No State-Law Protection

- AO 26-16 addresses federal fraud-and-abuse authorities and does not resolve state-law restrictions.
- California operators, for example, should separately evaluate Business and Professions Code Section 650, Welfare and Institutions Code Section 14107.2, applicable Medi-Cal patient-inducement, and free-goods restrictions, and, where applicable, the Knox-Keene Health Care Service Plan Act.

Material Facts Still Matter

- Material facts remain central. Changes in funding, benefit value, duration, eligibility criteria, marketing, payer selection, cost-sharing practices, vendor relationships, clinical integration, data sharing, or operational structure may materially alter the risk analysis.
- Organizations adapting the model should prepare a written comparison between their proposed arrangement and the facts underlying AO 26-16 rather than treating the opinion as a template that can be adopted without modification.

Before You Launch: Turning the OIG Roadmap Into A Practical Launch Plan

AO 26-16 is best used as a pre-launch program design and compliance blueprint. Organizations should build an audit-ready record before implementation—not after a complaint, audit, or enforcement inquiry.

1. Map the Program to the OIG Factors

- Prepare a written fraud-and-abuse analysis that documents how clinical eligibility, in-kind limits, cost-sharing, funding sources, and vendor controls align with the OIG's risk-reducing features.

2. Confirm Program Authority

- Verify the organization's authority to offer and fund the benefit, including scope-of-project, managed-care, supplemental-benefit, CalAIM, community-benefit, or other applicable authorities.

3. Establish Funding, Eligibility, and Cost-Sharing Controls

- Maintain accounting separation between funding sources;
- Document clinical and financial-need eligibility; and
- Preserve applicable patient cost sharing.

4. Strengthen Vendor and Privacy Controls

- Incorporate redemption limits, receipt monitoring, reporting obligations, audit rights, permitted items, privacy requirements, and data-use restrictions into vendor agreements.
- Execute BAAs where necessary and apply minimum-necessary standards when sharing information with third parties.

5. Measure and Document Outcomes

- Establish baseline, interim, and final measures for target clinical outcomes to demonstrate that the program is designed to advance patient care rather than referral volume or value.

6. Conduct Arrangement

- Specific State-Law Review. For PACE, Medicare Advantage, D-SNP, and CalAIM programs, confirm applicable benefit authority, eligibility, plan-of-care, marketing, and vendor requirements.
- Conduct a separate state-law review, including applicable kickback, free goods, patient-inducement, and corporate-practice requirements.

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7. Plan for Funding Transitions

- If relying on grant funding, document a transition plan for when funds are exhausted and evaluate any alternative funding source for potential cross-subsidization concerns.

8. Consider a Program-Specific Advisory Opinion

- If the program value is substantial or varies significantly from AO 26-16 facts, request a tailored OIG advisory opinion.
- If the proposed program materially differs from AO 26-16 or involves substantial benefit value, consider whether a program-specific OIG advisory opinion is warranted.

How Hinshaw Can Help

Organizations considering a food-as-medicine initiative should evaluate the program as an integrated legal and operational model and compare its material features with those addressed in AO 26-16.

Hinshaw Attorneys Assist Clients With

- **Conducting program-specific fraud-and-abuse, billing, privacy, and state-law risk assessments,** including AKS, CMP, and Stark Law analysis.
- **Evaluating program authority**, including scope-of-project requirements, managed-care and supplemental-benefit rules, community-benefit considerations, and related regulatory requirements.
- **Designing and implementing eligibility,** financial-need, benefit, funding, vendor, privacy, documentation, and outcome-measurement controls.

Where appropriate, Hinshaw can also structure and negotiate vendor, payer, provider, retailer, and arrangements for meal vendors, voucher administrators, and community-based organizations; prepare related compliance and governance materials; and assess whether a program-specific OIG advisory opinion request is warranted.

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Michael A. Dowell

Partner

213 614-7341

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