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# FOOD BANKS AS PARTNERS IN HEALTH PROMOTION

## Navigating Patient Inducement Laws


CHLPI CENTER for HEALTH LAW and POLICY INNOVATION HARVARD LAW SCHOOL

Health Law Lab
Innovating to address the social determinants of health

HUNGER + HEALTH | FEEDING AMERICA

## ABOUT THIS RESOURCE

This resource is intended for educational purposes only, to support food banks, food pantries, and other community-based organizations working with health care organizations to provide food-related supports to patients. The resource does not provide specific legal advice or legal representation. For specific legal questions, please consult an attorney.

## ABOUT THE AUTHORS

**CHLPI** The Center for Health Law and Policy Innovation of Harvard Law School (CHLPI) advocates for health and food justice, with a focus on the needs of systemically marginalized individuals. CHLPI works with a range of stakeholders to expand access to high-quality health care and nutritious, affordable food; to reduce health and food-related disparities; and to promote more equitable and sustainable health care and food systems.

CHLPI's Health Law Lab advances health care system efforts to address social determinants of health and health-related social needs, improve health equity, and mitigate health disparities.

**Feeding America** Feeding America® is the largest domestic hunger-relief organization in the United States. Through a network of 200 food banks and 60,000 food pantries and meal programs, we provide meals to more than 40 million people each year. Feeding America also supports programs that prevent food waste and improve food security among the people we serve; educates the public about the problem of hunger; and advocates for legislation that protects people from going hungry. Individuals, charities, businesses and government all have a role in ending hunger.

## ACKNOWLEDGMENTS

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# INTRODUCTION

Food banks are increasingly working with health care providers to address the intersections of food insecurity and health. Partnership activities are wide ranging and have included establishing food pantries at health care sites. However, food banks engaged in this work may encounter questions about a complex area of federal health care law: illegal patient inducements.

The first part of this resource, *Understanding the Legal Challenges,* provides an introduction to relevant federal law and why this area of law matters to health care organizations working to support the food security needs of their patients. The second part of this resource, *Navigating Legal Challenges*, offers strategies for food banks to engage health care provider partners in working through legal challenges to establish impactful food-related initiatives.

Importantly, health care organizations **can** respond to food insecurity among their patients **and** comply with the law—and many do. However, there is no single program design that will be the best fit for every health care provider organization. Not only has the law been evolving in recent years, but legal requirements differ based on the compliance pathway pursued, and health care providers interpret the law in different ways. As a result, food banks may find that what partners are comfortable with—the parameters to program design that partners insist on having in place—vary across initiatives.

This resource is intended to support food banks throughout partnership development by empowering them to:

- better understand the complexity of the legal landscape facing health care provider partners;
- recognize a partner's position on the law and the driving force behind certain programmatic limits or other features that a partner may pursue;
- highlight ways in which the law applies in the context of food-related supports that a partner may not be familiar with;
- identify relevant sources of information and follow evolutions in the legal landscape that impact program design; and
- support efforts to better enable the health care system to address the food-related needs of patients.

# UNDERSTANDING THE LEGAL CHALLENGES

### WHAT DOES FEDERAL LAW PROHIBIT?

When discussing a new program or initiative that provides food to patients, health care providers may be concerned about potential violations of two different but related laws addressing health care fraud and abuse: the **Anti-Kickback Statute (AKS)** and the **Civil Monetary Penalties Law (CMPL) Prohibition on Beneficiary Inducements.**

Both of these laws limit the circumstances in which health care providers can offer items or services for free or at a discounted rate to federal health care program patients, such as people enrolled in Medicaid or Medicare. These laws exist because of concerns that providing free or discounted items and services to Medicaid and Medicare beneficiaries has the potential to distort health care decision-making by patients (resulting, for example, in a patient seeking and receiving additional, unnecessary billed services). This distortion is known as **inducement.**

| Law | Description |
|---|---|
| **Anti-Kickback Statute (AKS)**<br>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 (e.g., Medicare, Medicaid). |
| **Civil Monetary Penalties Law (CMPL) Prohibition on Beneficiary Inducements**<br>42 U.S.C. § 1320a-7a | Generally prohibits offering free or discounted items or services to a federal health care program beneficiary (e.g., a person enrolled in Medicare or Medicaid) that are **likely to influence** the beneficiary's selection of a particular provider, practitioner, or supplier. |

### WHY DOES THIS IMPACT FOOD-RELATED SUPPORTS?

Food-related supports provided by a health care organization likely involve providing food for free or at a discounted rate unless the support is (a) a covered benefit under a health care program; (b) limited to screening for food insecurity and referring patients to a community-run food program; or (c) limited to enrollment assistance in government nutrition programs such as the Supplemental Nutrition Assistance Program (SNAP) and the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). As a result, initiatives that fall outside of these three scenarios can raise a red flag for health care providers (and their legal teams) who are wary of illegal inducements.

## ARE HEALTH CARE PROVIDERS EVER ALLOWED TO PROVIDE FREE OR DISCOUNTED ITEMS AND SERVICES TO PATIENTS?

Yes. There are several nuances to the law that enable health care providers to provide different items and services at no cost or reduced cost to patients. Specifically, health care providers consider:

1. **Does the CMPL Prohibition on Beneficiary Inducements apply?**
2. **Does the provision of free/discounted items or services fall into a category of protected arrangements (i.e., a safe harbor or exception)?**
3. **Even if the initiative is not protected by a safe harbor or exception, does it violate the law?**

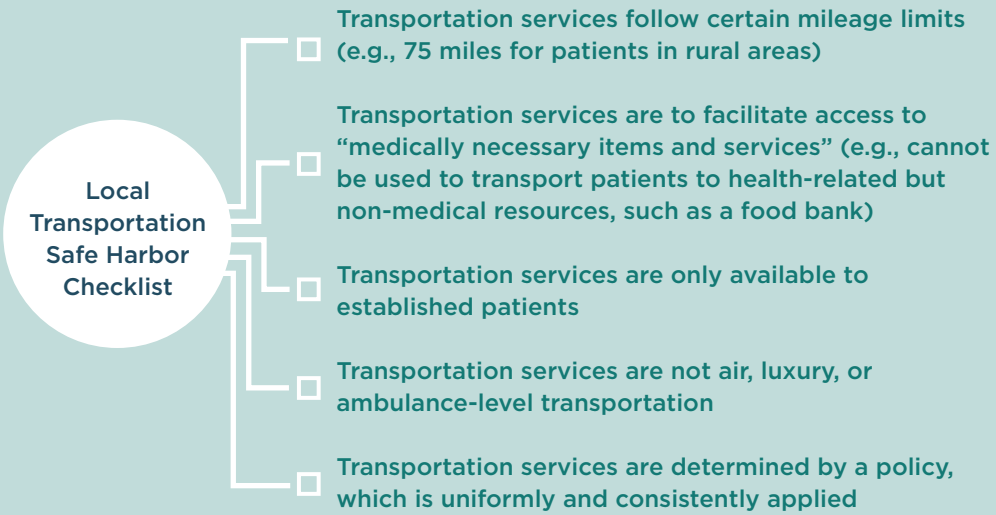
1. **Does the CMPL Prohibition on Beneficiary Inducements apply?** The CMPL Prohibition on Beneficiary Inducements does not apply to **items or services of nominal value**—currently defined by the federal government as something with a retail value of no more than $15 per item or $75 in the aggregate per patient per year.

2. **Does the provision of free/discounted items or services fall into a category of protected arrangements (i.e., a safe harbor or exception)?** The federal government recognizes that some arrangements that look like inducements pose a low risk of harm and are ultimately beneficial. In response, the government has created safe harbors that exempt certain arrangements from AKS and CMPL liability and additional exceptions to the CMPL. To minimize the risk of fraud and abuse, safe harbors and exceptions have several **conditions**—requirements that must be met as a condition for immunity.

At this time, there is no safe harbor or exception that focuses only and specifically on the provision of food-related supports to patients. Instead, health care organizations develop initiatives to comply with safe harbors or exceptions designed to achieve more broadly focused goals (e.g.,

### EXAMPLE: THE LOCAL TRANSPORTATION SAFE HARBOR

In 2016, the federal government created a new safe harbor for transportation services. This means that a health care provider can provide free or discounted transportation services to patients without a risk of AKS or CMPL liability under certain circumstances. The initiative must meet all of the safe harbor requirements, examples of which are given in the diagram.



helping patients with financial need access supports to improve health status). These pathways, with accompanying opportunities and challenges, are described in more detail under Navigating Legal Challenges.

3. **Even if the initiative is not protected by a safe harbor or exception, does it violate the law?** Just because an initiative does not fit within the confines of a safe harbor or exception does not mean that it necessarily violates the law or that the federal government would enforce penalties. This determination is case-specific and based on the facts and circumstances surrounding the initiative. In order to analyze an initiative's permissibility under the law, a health care organization's legal or compliance team will often compare it to past arrangements considered by the federal government.

   During this analysis, teams might ask questions like: Based on similar situations, what do we know about what is or is not allowable? Are there clearly defined rules to follow? If not, what kinds of initiatives or features of an initiative might pose a lower risk of harm (i.e., a lower risk of harmful inducement)? What about a higher risk of harm?

## EXAMPLE: ADDRESSING FOOD INSECURITY AND OTHER HEALTH-RELATED SOCIAL NEEDS DURING THE COVID-19 PANDEMIC

The federal government (specifically the Department of Health and Human Services Office of Inspector General, or OIG) regularly reviews and comments on the legality of proposed arrangements submitted by interested members of the public, such as health care systems.

As rates of food insecurity and other health-related social needs grew during the COVID-19 pandemic, health care providers across the country were called upon to support patients in new ways. A safety net provider (a health center that provides a significant level of care to people who are uninsured, people with Medicaid, and other vulnerable patients) asked the OIG whether they could provide "cash-equivalent" gift cards to certain patients.[1]

Cash equivalents are items that are easily converted to cash (e.g., a check) and items that are used like cash (e.g., a general purpose debit card)—and are typically viewed by the federal government as posing a high risk of harm when it comes to fraud and abuse. As a result, health care providers are usually prohibited from providing them to patients under patient inducement laws. Even so, regulators approved the arrangement.

In approving the arrangement, the OIG recognized the need to significantly relax its position on inducements during the public health emergency. The OIG also recognized that safety net providers are "well-positioned to identify [patient needs] and provide assistance to patients to address social determinants of health (e.g., food insecurity, housing instability, and transportation)."

# NAVIGATING LEGAL CHALLENGES

The three approaches to compliance described above fall along a spectrum in terms of organizational risk tolerance. This means that some health care providers are most comfortable providing supports that are at or under the nominal value limit because the requirements for compliance are the most straightforward: if the supports do not exceed $15 per item or $75 in the aggregate per patient per year there is no risk of a violation. Health care providers may be least comfortable developing an initiative that is not explicitly permissible under a safe harbor or exception.

At the same time, adherence to the nominal value threshold significantly restricts the potential impact of an initiative. Safe harbors and exceptions are constrained by conditions that may also limit impact. These and other trade-offs between the approaches are highlighted in the diagram below. More information on safe harbors and exceptions that can be used

## APPROACHES TO PROGRAMMING

RISK POTENTIAL

POTENTIAL IMPACT

| | Support is under the threshold nominal value limit | Support fits neatly within the parameters of a safe harbor or exception | Support does not fit into a safe harbor or exception |
|---|---|---|---|
| LEGAL RISK | No concern about legal liability because CMPL is not triggered | Immune from liability as long as all applicable requirements of the safe harbor or exception are strictly satisfied | No assurance of immunity from liability, but can be designed to minimize risk of violation |
| LIMITS ON PROGRAM DESIGN | Value of supports strictly limited to $15/item and $75/year | Conditions that attach to safe harbors and exceptions may limit who is eligible for support, circumstances for eligibility, and the types of support that can be provided | No strict limits—health care organization has to decide whether and how to implement limits to minimize risk of violation |
| CLARITY OF REQUIREMENTS | Very clear rules that must be followed | Some conditions are very straightforward—it is easy to understand what is required to satisfy the condition<br>Other conditions are less straightforward and the parameters—what is allowable in the context of providing food-related supports—are less clear | No strict rules to follow—health care organization has to decide whether and how to implement limits to minimize risk of violation |

to provide food-related supports is on page 9. Taking into account the legal landscape, food banks and health care organizations can work together to navigate patient inducement laws and provide high-impact food-related supports to patients.

**Strategies for forging a successful partnership include:**

1. **Involve a health care provider partner's legal and/or compliance team early in the partnership development process.**
2. **Explore whether the goals of the initiative can be met while satisfying all of the conditions of a safe harbor or exception, such as one of the options reviewed on page 9.**
3. **Be mindful of potential programmatic red flags, including those listed on page 10.**

1. **Involve a health care provider partner's legal and/or compliance team early in the partnership development process.** Health care organizations typically have strict policies regarding inducements, which usually require their staff to get approval from legal/compliance offices before free items or services can be provided to patients. Involving these teams early reduces the risk that the initiative will get held up by legal concerns at the last minute. Food banks can help decision-makers understand the importance of what the organizations are working on together and what it will take to make the initiative successful.

2. **Once the goals of the initiative are identified, explore whether those goals can be met while satisfying all of the conditions of a safe harbor or exception.** While there are many safe harbors and exceptions that shield arrangements from liability, they are not all relevant to the development of a food-related initiative. Moreover, among the safe harbors and exceptions that are relevant, some may be more relevant than others based on, for example, the specific goals of a partnership and/or attributes of a health care provider.

Safe harbors and exceptions commonly used by health care organizations to provide some form of food-related support to patients are identified and explored in the table below.

In reviewing this material, readers should keep in mind the following:

- The table reviews *some* of the key conditions that must be satisfied in order to secure immunity from liability. The table *does not* provide an exhaustive list of conditions. Complete lists can be accessed via materials cited.
- Many conditions are subject to interpretation and require a fact-specific analysis (e.g., where there is a requirement that the cost of an intervention is not "too large" compared to the value of the service).
- It is not always clear what falls within and outside the bounds of acceptable action in the context of food-related supports. To aid in the identification of potential parameters, the table highlights available commentary from the federal government on whether or not a contemplated arrangement involving food-related support satisfies requirements for immunity. These examples use language provided by the federal government.

| Safe Harbor /Exception | High-Level Description | Permissible Forms of Support | Potential Limitations to Consider |
|---|---|---|---|
| **Safe harbor for Centers for Medicare and Medicaid Services (CMS) model arrangements**[2] | Allows health care organizations in a **CMS-sponsored model** to provide free or discounted items to patients to advance a goal of the CMS-sponsored model<br>• CMS-sponsored models are Medicare Shared Savings Program Accountable Care Organizations (ACOs), the Medicare Diabetes Prevention Program, and other health care delivery and payment models tested by the CMS Innovation Center.<br>The safe harbor builds on earlier waivers of fraud and abuse laws for CMS-sponsored models. | • Depends on the CMS-sponsored model<br>• Example: According to the federal government, providing meal program vouchers to address malnutrition is an allowable incentive by Medicare Shared Savings Program ACOs.[3]<br>• Example: According to the federal government, providing 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.[4] | • Depends on the CMS-sponsored model<br>• Example: According to the federal government, 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.[5] |
| **Patient engagement and support safe harbor**[6] | Allows certain health care organizations to develop programs to support, among other goals, the prevention or management of a condition<br>Program must be designed around a "target population" (e.g., patients with chronic diabetes or another specific illness) | • In-kind items, goods or services (e.g., on-site food pantries, food vouchers) are permissible.<br>• Cash or cash equivalents (e.g., general purpose gift cards) are impermissible. | • The aggregate retail value of tools and supports provided to a patient cannot exceed $500 per year (2020 dollars), adjusted for inflation.[7] |
| **Financial need-based exception**[8] | Allows health care organizations to develop programs to help patients with financial need access items and services that support better health outcomes | • In-kind items, goods, or services (e.g., on-site food pantries, food vouchers) are permissible.<br>• Cash or cash equivalents (e.g., general purpose gift cards) are impermissible. | • There must be a connection between the item/service and a patient's medical care.<br>• The cost of the intervention cannot be "too large" compared to the value of the service.<br>• Example: According to the federal government, "providing meal deliveries for a limited period of time after a patient is discharged following a debilitating procedure might be reasonable from both a medical and financial perspective."[9]<br>• Example: According to the federal government, "paying for a subscription to a long-term meal delivery service" for a patient with diabetes is not reasonable from a financial perspective.[10] |
| **Preventive care exception**[11] | Allows health care organizations to provide incentives to patients to access eligible preventive health care services, including prenatal services and well-baby visits | • Many forms of incentives are permitted, and they do not need to be related to the health care service. | • This exception only protects programs built around a limited number of specified preventive health care services.<br>• The cost of the incentive cannot be "too large" compared to the value of the service. |
| Promotes access to care exception[12] | Allows health care organizations to provide various supports to address socioeconomic, geographic and other barriers to accessing care | • In-kind items, goods, or services (e.g., on-site food pantries, food vouchers) that promote access to care and pose a low risk of harm to patients and to health care programs are permissible.<br>• Cash or cash equivalents (e.g., general purpose gift cards) are impermissible.<br>• Example: The federal government approved an arrangement that provides 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 as permissible under this exception.[13] | • This exception does not protect supports that promote health and well-being more generally.<br>• Example: According to the federal government, food vouchers/meal services to "promote access to healthy living" do not meet the requirements of the exception and are not protected.[14] |

3. **Be mindful of potential programmatic red flags.** Certain programmatic features are more likely to be a red flag for health care providers, while others are typically associated with a lower risk of harm for fraud and abuse. When it comes to food-related initiatives, important safeguards may include:

   (a) **Eligibility for assistance is not tied to business**. The federal government is wary of arrangements that base eligibility on a person's past or anticipated use of a health care provider's health care services.

   
   Assistance should not be conditioned on a person agreeing to become or to continue as a patient of the health care provider.

   (b) **The initiative is not advertised.** The government generally prohibits advertising assistance programs because of concerns that advertisement will steer or coerce people toward other reimbursable services.

   
   Although "whether a particular means of communication constitutes an advertisement or solicitation will depend on the facts and circumstances,"[15] providing basic information relating to available supports does not violate marketing prohibitions.[16] It is therefore acceptable for a hospital food pantry to post its hours of operation.[17]

   
   Screening patients for a need opens the door to informing eligible patients about related supports available to them without advertising the program to the general patient population.

   (c) **The initiative provides in-kind assistance.** The government is generally more wary of the provision of cash than it is of non-monetary assistance.

   
   The government accepts vouchers for a specific type of support (e.g., a food voucher) as an acceptable approach to structuring an in-kind arrangement.[18]

   
   A general purpose debit card, on the other hand, is not an acceptable approach.[19]

   (d) **Implementation is accountable to written policies and documentation.** Documenting the intent of the program, safeguards built into the program and how they are operationalized, and processes to monitor adherence to the policies demonstrate a commitment to minimizing the risk of noncompliance.

   
   Policies should be uniformly and consistently applied.

In many instances, these kinds of guardrails are requirements for relying on a specific safe harbor or exception for immunity from liability. Building these kinds of guardrails into an initiative may also help lower the risk of a misstep in the eyes of the law when an initiative is not protected under a safe harbor or exception.

# CONCLUSION

Working together, food banks and health care organizations can both comply with the law and promote the health and well-being of the people they serve in new and creative ways.

As partners align on the design of initiatives to address the food and nutrition needs of communities, an understanding of laws prohibiting patient inducements and how to establish supports for patients in a legally compliant manner helps to ensure successful partnerships and related activities.

Food banks can stay connected to Feeding America and the Center for Health Law and Policy Innovation to follow developments in the law, share their experiences, and identify opportunities to advance legal reforms that improve ways in which the health care system responds to food insecurity.

## ADDITIONAL RESOURCES

The Feeding America Health and Nutrition Team has created additional tools to support food banks and their health care partners in their work to improve food security, diet quality, and other outcomes for people served by these partnerships.

**HUNGER + HEALTH** HungerandHealth.org, a website by Feeding America, developed out of a call from professionals to access and share quality information, tools, and resources addressing the root causes of food insecurity and social determinants of health.

**THE FEEDING AMERICA FOOD BANK - HEALTH CARE PARTNERSHIPS TOOLKIT** This toolkit was designed to help food banks build knowledge and capacity to expand partnerships with local health care organizations. This resource is available to Feeding America network food banks.

**YAMMER: HEALTH CARE PARTNERSHIPS DISCUSSIONS** This Yammer page is for food bank staff to share feedback, post questions, and highlight updates on working with health care organizations. This resource is available to Feeding America network food banks.

## ENDNOTES


1 US Department of Health and Human Services, Office of Inspector General. FAQs–Application of OIG's Administrative Enforcement Authorities to Arrangements Directly Connected to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency. Washington: US Department of Health and Human Services, Office of Inspector General. Last updated 2021 May 5. Available from: https://oig.hhs.gov/coronavirus/authorities-faq.asp.

2 42 C.F.R. § 1001.952(ii). *See also* 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. Final Rule. Fed. Regist. 2016 Dec 7; 81(235): 88368-88409; Available from: https://www.federalregister.gov/documents/2016/12/07/2016-28297/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-the-safe-harbors-under-the.

3 42 C.F.R. § 425.304.

4 *See* Medicare Learning Network. Medicare Diabetes Prevention Program: supplier enrollment call. Washington: Centers for Medicare & Medicaid Services; 2018 Jun 20 [cited 2021 Mar 29]. 26 p. Available from: https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2018-06-20-MDPP-Transcript.pdf; National Diabetes Prevention Program. Working with Medicare beneficiaries guide for CDC-recognized organizations. Washington: Centers for Disease Control and Prevention; [cited 2021 Mar 29]. 21 p. Available from: https://www.cdc.gov/diabetes/prevention/pdf/ta/Implementation-Guide-Medicare.pdf.

5 *See* 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. Final Rule. Fed. Regist. 2017 Nov 15; 82(219): 53331; Available from: https://www.federalregister.gov/documents/2017/11/15/2017-23953/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions.

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7 The federal government will publish an announcement on the Department of Health and Human Services Office of Inspector General website "after September 30 of each year" reflecting the monetary cap applicable for the next calendar year. 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. Final Rule. Fed. Regist. 2020 Dec 2; 85(232): 77684-77894; Available from: https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

8 42 C.F.R. § 1003.110(8). *See also* 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. Final Rule. Fed. Regist. 2016 Dec 7; 81(235): 88368-88409; Available from: https://www.federalregister.gov/documents/2016/12/07/2016-28297/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-the-safe-harbors-under-the; 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. Final Rule. Fed. Regist. 2020 Dec 2; 85(232): 77684-77894; Available from: https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the.

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11 42 C.F.R. § 1003.110(8).

12 42 C.F.R. § 1003.110. *See also* 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. Final Rule. Fed. Regist. 2016 Dec 7; 81(235): 88368-88409.

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