

Prioritizing People: Health Care Fraud & Abuse Law Flexibility During COVID-19

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As communities across the country continue to grapple with the consequences of COVID-19, the health care system is called upon to support social determinants of health (SDOH). While compliance with health care fraud and abuse laws can be a barrier to some types of support, this blog post explores considerations raised by recent feedback from the U.S. Department of Health and Human Services Office of the Inspector General (OIG). Through the feedback, OIG communicates recognition of the urgency for SDOH interventions and the need for common-sense flexibility during the public health emergency.

Enforcers Weigh in on Compliance with Health Care Fraud and Abuse Laws

OIG, the division responsible for enforcing federal health care fraud and abuse laws, has published feedback on navigating the federal [Anti-Kickback Statute and the prohibition on inducements to federal health care program beneficiaries](#) in light of COVID-19. The feedback is provided as a series of [Frequently Asked Questions](#) in which the OIG evaluates the risk of legal noncompliance associated with various proposed arrangements.

Federal Law

- The **Anti-Kickback Statute** ([42 U.S.C. § 1320a-7\(b\)](#)) generally prohibits knowingly and willfully offering, paying, soliciting or receiving anything of value to induce or reward referrals for items/services payable under a federal health care program. Safe harbors exempt certain arrangements from liability.
- The **Civil Monetary Penalties Law prohibition on beneficiary inducements** ([42 U.S.C. § 1320a-7a](#)) generally prohibits offering something of value to a federal health care program beneficiary that is likely to influence the beneficiary's selection of particular providers, practitioners, or suppliers, unless the transaction fits within an exception.

OIG has addressed a number of proposals in which health care providers seek to support the social determinants of health of their patients by providing them with free or discounted items and services. Questions presented highlight the impact of COVID-19 on transportation to medical care, food insecurity, housing instability, consequences from closures of nonprofit lodging facilities that support patients who get cancer treatment far from home, and inequity in access to telecommunications technologies.

Importantly, for each such proposed arrangement with which OIG has reckoned—under the facts presented to it and subject to certain conditions—OIG has concluded that the intervention is associated with a low risk of fraud and abuse.

Providing Cash-Equivalent Gift Cards to Support Patient SDOH

In its most recent assessment, OIG tackles the following question: A Federally Qualified Health Center (FQHC) received from a private foundation a \$15,000 COVID-19 relief grant designated for emergency cash assistance for financially needy individuals. Can the FQHC furnish cash-equivalent gift cards, in specified amounts, to address social determinants of health for financially needy individuals, including federal health care program beneficiaries who meet certain criteria?

Cash, cash equivalents, and gift cards

Historically, OIG has been especially concerned with the provision of cash and cash equivalents to federal health care program (i.e., Medicaid and Medicare) beneficiaries. Cash equivalents are items that are easily converted to cash (e.g., a check) or that are used like cash (e.g., a general-purpose debit card).¹ While OIG does not see gift cards that can be redeemed only at a certain store or for a certain purpose (such as a gas card) as cash, it appears that the organization requesting feedback from OIG wants to give patients something more like a general-purpose debit card.

OIG indicates that the FQHC's proposal to distribute cash-equivalent gift cards to federal health care program beneficiaries presents a low risk of fraud and abuse based on several attributes of the arrangement:

- (1) The COVID-19 relief grant was specifically designated for emergency cash assistance to individuals.
- (2) Distribution of grant funds would be administered through one of the FQHC's social services programs.
- (3) The FQHC would screen for financial need and for COVID-19-related financial need. The FQHC would also document a person's satisfaction of these two requirements.

Screening for financial need

In general, OIG does not set a level at which people qualify as being in need of financial assistance or mandate any specific manner of determining financial need. These decisions are left to individual health care organizations. OIG does, however, explicitly state that financial need can be demonstrated by an individual's enrollment in Medicaid.

With respect to COVID-19-related financial need, the FQHC in this example would screen individuals to confirm that they have lost more than 50% of their income due to the public health emergency.

- (4) The gift cards would not be conditioned on a person's past or anticipated future use of the FQHC's services. The FQHC would explain to a recipient that their eligibility for the assistance is not tied to becoming a patient of the FQHC or, for existing patients, continuing to receive care from the FQHC. Further, the FQHC would require a signed acknowledgment to this effect from each recipient.
- (5) The FQHC would limit its cash assistance to a one-time gift card in the amount of \$100-\$200 (depending on family size). The FQHC would track recipients to ensure that patients only receive one round of assistance.
- (6) The FQHC would not advertise the program.

Limits to the OIG Assessments

Health care organizations looking to support patients in a manner modeled on the OIG's COVID-19 assessments should take into account the following limitations:

- OIG refers to the feedback as informal and nonbinding, and OIG is not offering prospective immunity. This means that there is, at least theoretically, some level of risk involved in rolling out a similar arrangement.
- The OIG analyses are specific to the set of circumstances considered and subject to any guardrails that OIG emphasizes in its response.
- The analyses are limited to the duration of the COVID-19 emergency declaration.
- The OIG analyses do not address any other federal law, or any state or local law.

The Bigger Picture: Implications for SDOH Interventions During COVID-19

OIG clearly recognizes the urgency of SDOH interventions and the need for regulatory flexibility during the public health emergency. The FAQs indicate a willingness on the part of OIG to review a broad range of interventions through a sensible and practical lens.

We encourage health care organizations to seize the opportunity before them—to consider the needs of their patients and the communities in which they serve, and to stand up innovative programs that respond to those needs.

We offer the following compliance considerations:

- Is the Civil Monetary Penalties Law prohibition on beneficiary inducements even implicated? If the provision of an item or service is not likely to influence a beneficiary to choose a particular federal health care program provider, practitioner, or supplier, then the law is not triggered. Additionally, the provision of items/services of **nominal value** does not trigger the law. (OIG policy sets nominal value at a retail value of no more than \$15 per item and \$75 per patient on an annual basis). Note, however, that a separate analysis of the Anti-Kickback Statute may be warranted.
- Review existing exceptions and safe harbors, such as the financial need exception² and the transportation safe harbor.³ Can you develop a program that satisfies the relevant criteria?
- Just because an intervention does not fit within the confines of an existing exception or safe harbor does not mean that it necessarily violates law. That analysis is based on specific facts and circumstances. Identify safeguards—elements of arrangements that OIG highlight as contributing to a low risk of fraud and abuse. The more you can build into your program, the better. Some common safeguards advanced by OIG include:
 - **Eligibility for assistance is not tied to business:** OIG is wary of arrangements that base eligibility in a manner that takes into account 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 a patient or agreeing to continue as a patient.
 - **In-kind assistance:** OIG is more wary of the provision of cash than it is in-kind assistance. The use of a voucher system (e.g., food vouchers, transportation vouchers) is a common approach to structuring an in-kind arrangement.
 - **Advertising:** OIG generally prohibits advertising assistance programs. Screening patients for a need opens the door to informing eligible patients about related supports available to them without advertising the program.
 - **Reasonableness:** OIG is more wary of the provision of luxury items or services than it is more modest forms.
 - **Written policies and documentation:** Documenting the intent of the program, safeguards you have incorporated into your program, how you operationalize those safeguards, and how you monitor/support adherence to your policies helps demonstrate a commitment to minimizing the risk of noncompliance.
- Need additional confirmation? organizations have the option to submit a specific inquiry to OIG at OIGComplianceSuggestions@oig.hhs.gov.

Disclaimer

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References

- 1 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kick-back Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88393 (December 7, 2016).
- 2 42 C.F.R. § 1003.110(8).
- 3 42 C.F.R. § 1001.952(bb).

The 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. We work to realize a coordinated system of comprehensive care that recognizes the foundational role of social determinants of health in improving health outcomes, shaping individual and community experiences of health care, and reducing health care costs. The Health Law Lab explores, analyzes, and nurtures innovations that address social determinants of health, and examines the legal, regulatory, and policy implications of integrating these interventions into health care delivery and financing.

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