NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS®

Issue Brief

Structuring Patient Incentive Programs to Minimize Risk Under Federal Laws

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Patient incentives are broadly recognized as important tools to promote healthy behaviors, increase visits for primary and preventive services, and encourage participation in research studies.[1] Despite these benefits, certain federal laws have long posed a challenge to health centers seeking to implement patient incentive programs. The purpose of this Issue Brief is to describe federal laws implicated by patient incentive programs and to identify potential ways that health centers can structure patient incentive programs to reduce the risk of violating those laws.

BACKGROUND

The **Beneficiary Inducement Prohibition** of the Civil Monetary Penalties Law prohibits individuals or entities from offering or transferring "remuneration" to a federal health care program beneficiary that is likely to influence the beneficiary's selection of a provider or supplier for an item or service that is paid for in whole or part by federal programs such as Medicare, Medicaid, or CHIP.[2] "Remuneration" means anything of value, including free or below market value goods and services. Violations of the Beneficiary Inducement Prohibition can result in monetary penalties up to $24,164 (as set in 2023 and thereafter adjusted annually for inflation), plus three times the amount claimed from federal programs, and potential exclusion from participation in federal health care programs.

To determine whether a patient incentive implicates the Beneficiary Inducement Prohibition, consider the following three questions:

- **Is your health center proposing to offer something of value (i.e., remuneration) to patients covered by Medicare, Medicaid or CHIP?**
- **Is the remuneration likely to influence the patients' decision to receive goods and services from the health center?**
- **Are the goods or services paid for by Medicare, Medicaid or CHIP?**

If the answer to all three of the above questions is yes, then the patient incentive implicates the Beneficiary Inducement Prohibition.

The **Anti-Kickback Statute** prohibits persons or entities from knowingly and willfully soliciting or receiving remuneration, directly or indirectly, cash or in-kind, to induce patient referrals or the purchase or lease of equipment, goods, or services that are payable in whole or in part by Medicare, Medicaid or CHIP.[3] Remuneration specifically include kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind. Prohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by federal health care programs. Violations can result in criminal penalties punishable by a maximum fine of $100,000 and imprisonment of up to ten years, or both; exclusion from participation in federal health care programs; civil monetary penalties; and False Claims Act liability.

REGULATORY EXCEPTIONS AND SAFE HARBORS

Whenever a patient incentive implicates the Beneficiary Inducement Prohibition or Anti-Kickback Statute, health centers should seek to structure the program to fit within an existing regulatory exception or safe harbor in order to reduce the risk of potential violations.[4] In doing so, health centers should document compliance with each required element of the regulatory exception or safe harbor. The following exceptions and safe harbor frequently apply to patient incentive programs.

[1] Patients who serve as health center board members may participate in patient incentive programs, provided that such participation is on the same terms as any other patient. Receipt of such patient incentives do not constitute reimbursement of board members for expenses incurred by reason of their participation on the board described in 42 C.F.R. § 51c.107 and 42 C.F.R. § 56.108.

[2] 42 U.S.C. § 1320a-7a(5); 42 C.F.R. § 1003.1000(a).

[3] 42 U.S.C. 1320a-7b(b).

[4] Health centers may be already familiar with the Anti-Kickback Statute safe harbor that protects the transfer of goods, items, services, donations or loans from an individual or entity to a federally-funded health center when made in compliance with nine regulatory standards established by the Office of Inspector General (OIG). See 42 C.F.R. § 1101.952(w). This safe harbor would not protect patient incentives offered by a health center to its patients.

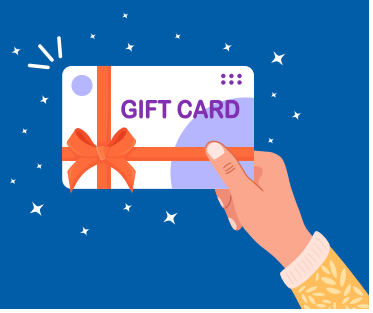
De Minimis (Nominal) Value "Exception"

The Office of Inspector General ("OIG") of the U.S. Department of Health & Human Services has taken the position that remuneration that is only nominal in value (*i.e.*, *de minimis*) is not prohibited by the Beneficiary Inducement Prohibition. The OIG has interpreted "nominal in value" to mean no more than $15 per item and no more than $75 in the aggregate per patient per year that are not cash or cash equivalents.[5] Cash equivalents are items that patients can convert to cash and be used for any purpose, such as gift cards from "big box" stores.[6] The nominal value "exception" is well-suited for patient incentives to promote healthy behaviors and encourage participation in research studies that use store-based gift cards falling within the dollar limits stated above.

Differentiating Between Cash, Cash Equivalents, and In-Kind Gift Cards

Under the OIG's recent interpretations[7]:

- "Cash" refers to monetary payments in the form of currency, including electronic payments, such as through a person-to-person application
- "Cash equivalents" include items convertible to cash (such as a check) or items that can be used like cash or diverted from their intended purpose such as a general-purpose prepaid card such as a Visa or Mastercard gift card or gift cards offered by large retailers or online vendors that sell a wide variety of items (*e.g.*, big-box stores)
- "In-Kind Gift Cards" include gift cards that can be redeemed only for certain categories of services or items (*e.g.*, a meal delivery service or gasoline), vouchers for a particular item or service (*e.g.*, a meal or taxi ride), or a gift card to a big-box store that limits use to a particular item or select categories of items (*e.g.*, the purchase of fresh food)



[5] In a free raffle, the OIG considers the value of the ticket, not the value of the prize, in determining whether the remuneration is of nominal value. For example, in a raffle involving a prize worth $100, if a person had only a 1 in 25 chance of winning, the value of the raffle ticket would be worth only $4, qualifying as nominal value. See 81 Fed. Reg. 88368, 88395 (Dec. 7, 2016).
[6] 85 Fed. Reg. 77,684, 77790 (Dec. 2, 2020).
[7] Office of Inspector General, General Questions Regarding Certain Fraud and Abuse Authorities", FAQ # 5 (last updated May 31, 2023).

Preventive Care Services Exception

As to the Beneficiary Inducement Prohibition, remuneration excludes incentives that promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed by federal health care programs.[8] Incentives may include the provision of preventive care itself but may not include cash or instruments convertible to cash or an incentive in which its value is disproportionally large in relationship to the value of the preventive care service (*i.e.*, either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

Health centers should recognize that not all services (*e.g.*, annual physicals) qualify for protection under the Preventive Care Services Exception. The regulatory definition of preventive care, for purposes of this exception, means any service that: (1) is a prenatal service or a post-natal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's Guide to Clinical Preventive Services and (2) is reimbursable in whole or in part by federal health care program.[9] Accordingly, only an annual physical that includes a specific clinical service recommended by the U.S. Preventive Services Task Force would meet the definition of preventive care.

EXAMPLE:

Healthy Food Vouchers Patient Incentive Program

- A health center advertises a program to incentivize preventive care screenings.
- Patients who receive recommended U.S. Preventive Services Task Force ("USPSTF") screenings at annual well child or well adult visits are eligible to receive $20 monthly vouchers for whole grains, fruit and vegetables at a local farmers market.

The **Preventive Care Services Exception** applies to this patient incentive program because the incentive promotes a USPSTF screening, is not tied to other services reimbursed by federal health care programs and is not disproportionately large compared to the value of the preventive service.

[8] 42 U.S.C. § 1320a–7a(i)(6)(D); 42 C.F.R. § 1003.110 (subsection (4) of the definition of "remuneration").

[9] 42 C.F.R. § 1003.110 (definition of "preventive care"). The OIG interprets the defined term "preventive care" to include any vaccine administered consistent with a current Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommendation on immunizations for children and adults, provided the vaccine is reimbursable by Medicare or an applicable State health care program. See OIG, General Questions Regarding Certain Fraud and Abuse Authorities, FAQ #12, available at https://oig.hhs.gov/faqs/general-questions-regarding-certain-fraud-and-abuse-authorities/.

Access to Care Exception

As to the Beneficiary Inducement Prohibition, remuneration excludes items and services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare, Medicaid, and beneficiaries.[10] Items or services present a "low risk of harm" if they are: (1) unlikely to interfere with, or skew, clinical decision making, (2) are unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization, and (3) do not raise patient-safety or quality-of-care concerns. Importantly, this exception does not require a health center to demonstrate the financial need of the patient.

Enabling services that remove barriers to care or make access to care more convenient to patients could fall within the Access to Care Exception if there is a low risk of harm. The OIG has stated that promoting access to care "encompasses giving patients the tools they need to remove" barriers to care.[11] This includes items or services that "mak[e] access to care more convenient for patients than it otherwise would be,"[12] but does not include "inducements to comply with treatment or rewards for compliance with treatment."[13]

EXAMPLE:

Enabling Services

Enabling services may be protected by the Access to Care Exception if they promote access to items and services reimbursable by Medicare or Medicaid and represent a low risk of harm to patients and those healthcare programs. Examples include:

- **translation/interpretation services**
- **eligibility assistance**
- **health literacy**
- **patient/community outreach**

Smartphone apps or low-cost fitness trackers could also promote access to care if they are used to track milestones and report data back to the treating physician.

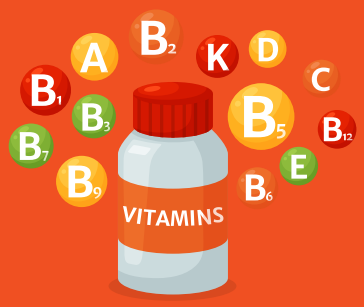
[10] 42 C.F.R. § 1003.110 (subsection (6) of the definition of "remuneration").
[11] 81 Fed. Reg. 88393.
[12] *Id.*
[13] *Id.* at 88394.

Financial Need Exception

As to the Beneficiary Inducement Prohibition, remuneration excludes items or services offered for free or at less than fair market value to individuals with demonstrated financial need when the items or services are: (1) not advertised; (2) not tied to the provision of other items or services reimbursed by Medicare or Medicaid; (3) reasonably connected to the medical care of the individual; and (4) transferred only after a good faith determination that the recipient is of financial need.[14] Items or services are "reasonably connected" to medical care when: (1) the items would benefit identifiable medical care or treatment that the individual patient is receiving; and (2) the value of the remuneration is reasonable, meaning not disproportionately large in value compared with the medical benefits conferred on the individual patient.[15] Determinations of financial need must be patient-specific and made on a case-by-case basis.[16]

In interpreting the "reasonably connected to medical care" requirement of the Financial Need Exception, health centers should be aware that the OIG has stated that items such as strollers, school supplies and clothing would not qualify under this exception, but glucose monitors, baby formula, diapers and specialized clothing could qualify, depending on the individual circumstances.[17]

Examples of Items and Services Related to Medical Care under the Financial Need Exception



- A pager to alert patients with mental illness to take their prescribed medication
- Free nutritional supplements to under-nourished patients
- Monitoring devices necessary to meet a patients' various mental health needs
- Low-cost patient engagement phone apps

[14] 42 C.F.R. § 1003.110 (subsection (8) of the definition of "remuneration").
[15] 81 Fed. Reg. 88403.
[16] Id. at 88405.
[17] Id. at. 88403.

Free and Discounted Local Transportation Safe Harbor

For purposes of both Beneficiary Inducement Prohibition and the Anti-Kickback Statute,[18] remuneration excludes transportation provided to "established patients" anywhere within a "local area" for purposes of obtaining medically necessary items or services.[19] To be protected under the safe harbor: (1) entities must have a set policy regarding the availability of transportation assistance, and the policy must be applied uniformly and consistently; (2) transportation must not be related to the past or anticipated volume or value of Federal health care program business; (3) the modes of permissible transportation must be limited and exclude air, luxury, and ambulance-level transportation; and (4) transportation assistance may not be publicly advertised or marketed to patients or others who are potential referral sources. Health centers may inform patients that transportation is available if it is done in a targeted manner.[20] For example, when a patient schedules a procedure that requires a safe ride home, the health center may ask if the patient has transportation.

Key Terms under the Free and Discounted Local Transportation Safe Harbor

"Established patient"
means an individual who has contacted the provider to schedule an appointment or has previously received care from the provider.

"Local area"
means a geographic radius of 25 miles in urban settings and 75 miles in rural areas.

CMS-Sponsored Model Patient Incentives Safe Harbor

For the purpose of both Beneficiary Inducement Prohibition and the Anti-Kickback Statute, remuneration excludes patient incentives authorized by the Centers for Medicare and Medicaid Services (CMS) for use in CMS-sponsored models and the Medicare Shared Savings Program if all of the following conditions are met: (1) the participant in the CMS-sponsored model reasonably determines that the patient incentive advances one or more goals of the CMS-sponsored model; (2) the patient incentive has a direct connection to the patient's health care unless the participation agreement expressly specifies a different standard; (3) the patient incentive is furnished by a participant (or its agent) in the CMS-sponsored model participant under the participant's direction and control); (4) the participant in the CMS-sponsored model makes available to the U.S. Department of Health and Human Services, upon request, all materials and records sufficient to establish whether the patient incentive was distributed in a manner that meets the conditions of this safe harbor; and (5) the patient incentive is furnished consistent with the CMS-sponsored model and satisfies such programmatic requirements as may be imposed by CMS in connection with the use of this safe harbor.[21]

[18] Any practice that is protected by an exception or safe harbor to the Anti-Kickback Statute also is excepted from the definition of "remuneration" under the Beneficiary Inducement Prohibition. 42 C.F.R. § 1003.110 (subsection (2) of the definition of "remuneration").
[19] 42 C.F.R. § 1101.952(bb).
[20] 81 Fed. Reg. 88387.
[21] 42 C.F.R. § 1001.952(ii)

OIG ADVISORY OPINIONS

Congress granted the OIG authority to issue binding advisory opinions regarding the application of the Beneficiary Inducement Prohibition or Anti-Kickback Statute to conduct that is not covered by existing statutory or regulatory exceptions.[22] When favorable, such advisory opinions provide the requesting party with immunity from the imposition of sanctions by the OIG. Although no other party may rely on an advisory opinion for legal protection, health centers that model their patient incentive programs on arrangements that received favorable advisory opinions incur a lower risk of violating the Beneficiary Inducement Prohibition and Anti-Kickback Statute.

Pediatric No-Show Incentive Program

On December 23, 2020, the OIG issued a favorable advisory opinion addressing a health center's proposal to use $20 gift cards to incentivize pediatric patients who had previously missed two or more preventive and early intervention care appointments to attend such appointments.[23] Despite neither Beneficiary Inducement Prohibition exceptions for the promotion of access to care nor the promotion of preventive care protecting the proposed arrangement, the OIG concluded, under its exercise of discretion, that it would not impose sanctions on the health center.

In reaching its decision, the OIG noted that:

- The risk of inappropriate patient steering would be minimized due to the narrowly defined pool of eligible patients and the risk that the gift card would induce eligible patients to select the health center for future appointments or other federally reimbursable items and services is low;
- The proposed arrangement would be unlikely to lead to increased costs to federal health care programs or patients through overutilization or inappropriate utilization;
- The proposed arrangement is unlikely to harm competition; and
- The scope of the proposed arrangement appears reasonably tailored to accomplish health center's goal of improving attendance rates at appointments.

Section 330 Legal Considerations

Health centers may use grant funds to offer patient incentives, as long as the associated costs are allowable under applicable federal grants regulations (45 C.F.R. Part 75) and the HHS Grants Policy Statement.[24] In accordance with Section 330(e)(5)(D) of the Public Health Service Act (PHSA), health centers may use non-grant funds (*e.g.*, program income) to offer patient incentives if such use furthers the objectives of the health center project and is not specifically prohibited under Section 330 of the PHSA.

Grant and non-grant funds pledged to the health center project that are used for patient incentives must be included in the annual budget approved by the Health Resources and Services Administration (HRSA). Further, program income in excess of the amounts pledged to the health center project (*i.e.*, "excess program income") may be used for patient incentives, provided that such use furthers the objectives of the health center project (*i.e.*, benefits the current or proposed patient population) and is not specifically prohibited under Section 330 of the PHSA.

Certain health center awards may impose additional limitations on the use of grant funds for patient incentives. For example, the Ending the HIV Epidemic – Primary Care HIV Prevention ("PCHP") funding opportunity allows health centers to use PCHP funds to offer patient-related incentives only if the incentives are documented and part of a clinically-proven program to be used in carrying out the project (*i.e.*, program provides a gift card of nominal value to purchase healthy food after an established patient attends a certain number of sessions).[25] PCHP funding may not be used to provide incentives (*e.g.*, gift cards, food) to encourage initial participation in patient education or HIV prevention services.[26]

[22] 42 U.S.C. § 1320a–7d(b); 42 C.F.R. Part 1008, Subpart A.
[23] Office of Inspector General of the U.S. Department of Health & Human Services, OIG Advisory Opinion No. 20-08 (Dec. 23, 2020), https://oig.hhs.gov/documents/advisory-opinions/771/AO-20-08.pdf.
[24] HHS Grants Policy Statement https://www.hhs.gov/sites/default/files/hhs-grants-policy-statement-october-2024.pdf
[25] HRSA, PCHP Frequently Asked Questions, available at https://bphc.hrsa.gov/funding/funding-opportunities/primary-care-hiv-prevention/pchp-faqs.
[26] Id.

Contingency Management Program

On March 8, 2023, the OIG issued a favorable advisory opinion addressing a digital health company's technology for a contingency management platform, an evidence-based approach for treating substance use disorders that uses financial incentives to reward healthy behavior, such as abstinence and treatment retention.[27] Although the arrangement did not satisfy an exception to the Beneficiary Inducements Prohibition or a safe harbor to the Anti-Kickback Statute, the OIG concluded that the Arrangement presented minimal risk of fraud and abuse.

In reaching its decision, the OIG noted that:

- The digital health company certified that the proposed arrangement is protocol-driven and is consistent with evidence-based research funded by NIH and principles for effective treatment of substance use disorders;
- The amount of remuneration is relatively low and are capped;
- The digital health company does not bill federal health care programs so the risk of contingency management incentives encouraging overutilization of federally reimbursable services or that their customers would pay fees to generate business or reward referrals of federally reimbursable services is low; and
- The proposed arrangement includes certain safeguards for the use of the smart debit cards that mitigate the risk of fraud and abuse.

Clinical Research Studies

The OIG has approved several arrangements involving waivers of cost-sharing obligations for research study participants when the risk of fraud of abuse is low, as evidenced by federal sponsorship of the research study, and an Institutional Review Board (IRB) has approved payments to research participants.[28]

CONCLUSION

In developing patient incentive programs, health centers should have a clear understanding of the target population and the conduct or behavior that it seeks to incentivize through the patient incentive program. Health centers should also consider the minimum dollar amount or value of the incentive that would be necessary for impacting the desired conduct or behavior.

As a threshold matter, health centers should first assess whether a proposed patient incentive implicates the Beneficiary Inducement Prohibition or Anti-Kickback Statute, and if so, whether the incentive complies with an existing regulatory exception or safe harbor. If the proposed incentive program would not comply with an existing regulatory exception or safe harbor, health centers should attempt to restructure the proposed incentive program to comply with the exception or safe harbor or to conform it to an arrangement previously approved by the OIG under an advisory opinion.

If is not possible to restructure the incentive program to comply with an existing exception or safe harbor, and it does not conform to a previously approved advisory opinion, a health center may wish to consider seeking a formal advisory opinion from the OIG to protect the health center from possible violations of the Beneficiary Inducement Prohibition or Anti-Kickback Statute. In all situations, health centers should document the incentive program in writing through policies and procedures, conduct staff training and education on the incentive program, and audit operational compliance with the policies and procedures.

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[27] Office of Inspector General of the U.S. Department of Health & Human Services, OIG Advisory Opinion No. 22-04 (March 2, 2022).
[28] Advisory Opinion No. 23-11; Advisory Opinion No. 22-05; Advisory Opinion No. 21-17; Advisory Opinion No. 21-13; Advisory Opinion No. 16-13; Advisory Opinion No. 08-11, Advisory Opinion No. 98-6.