Alerts

New OIG Guidance Permits Federally Qualified Health Centers to Offer Remote Patient Monitoring, Big-Box Store Gift Cards, and Other Incentives to Medicare and Medicaid Patients

February 22, 2021
Health Care Alert

Attorneys

Michael A. Dowell

Federally Qualified Health Centers (FQHCs) deliver care to some of the nation's most vulnerable individuals and families, including federal Medicare and Medicaid health care program beneficiaries. As safety net providers, FQHCs are well positioned to identify beneficiary hardships and to provide financial or in-kind assistance to patients to address social determinants of health such as access to health care, food insecurity, housing instability, and transportation.

The federal Anti-Kickback Statute (AKS) criminalizes knowingly and willfully offering or paying any remuneration to induce a referral of services reimbursable by a federal health care program. The Civil Monetary Penalty Law (CMPL) prohibits 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 of a federally reimbursable item or services.

The U.S. Department of Health and Human Services Office of Inspector General (OIG) has repeatedly confirmed that offering free or discounted items or services to government program patients potentially implicates the AKS and/or CMPL unless the program is structured to fit within a statutory or regulatory exception or certain safeguards are put in place to minimize program fraud and abuse. (*See*, *e.g.*, OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries).

FQHC's have routinely provided gifts and other in-kind assistance to patients to incentivize them to obtain preventive care, prescription drug adherence, or engage in other healthy behaviors. A few CMPL exceptions generally relied on by FQHCs for patient incentives include: (1) preventive care items or services; (2) items or services to promote access to care; (3) items or services of nominal value; or (4) the documentation of demonstrated financial need. The National Association of Community Health Centers (NACHC) noted the following in a proposal for the federal government to create a safe harbor for FQHC gifts to beneficiaries:

> *Some gifts and motivational incentives provided by health centers to encourage patients to seek timely and appropriate low-cost preventive and primary and to comply with necessary treatment regimens meet the [AKS and CMPL] requirements. However, due to the very nature of particular*

incentives, many are unable to do so. For example, one of the most effective ways in which to encourage compliance with children's immunization schedules is to provide parents with gifts cards for back to school items or other items related to the child's well-being. Similarly, providing diapers, formula, gift cards for baby items, and car seats have proven effective in encouraging compliance with prenatal regimens. Providing "every-day" necessities that are connected to either the patient's condition or the particular service or treatment he or she receives, and that are necessary for the general well-being of the patients and their families often alleviates the need for low-income patients to choose between receiving necessary health care services or obtaining other necessities. Notwithstanding their proven effectiveness in encouraging the appropriate level of care provided on a timely basis, arrangements to offer these types of incentives are not currently protected from prosecution without seeking an individual advisory opinion.

The NACHC proposal was not successful, however, the new OIG Guidance adopts many of its principles and expands the scope and types of patient incentives that FQHCs may provide. The OIG Guidance also adds clarity on what the OIG may interpret as prohibited activities.

New Anti-Kickback Safe Harbor: Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency

In December 2020, the OIG finalized a new safe harbor for arrangements for patient engagement and support to improve quality, health outcomes, and efficiency (42 CFR 1001.952(hh) (Safe Harbor)). The Safe Harbor allows a value-based enterprise (VBE) participant to provide in-kind patient engagement tools and supports to a patient in the target population of a value-based agreement—if the VBE is a participant to the agreement—provided that all other elements to the Safe Harbor are met. The Safe Harbor permits VBE participants to furnish patient engagement tools and supports directly to patients in a target patient population when those tools or supports advance: (1) a patient's adherence to a drug or treatment regimen; (2) a patient's adherence to a follow-up care plan; (3) the prevention or management of a patient's disease or condition; or (4) patient safety. The Safe Harbor imposes a $500 (retail value) annual, aggregate per-patient cap, and requires that the provision of the tool or support not result in medically unnecessary or inappropriate federally reimbursable items or services.

The types of renumeration eligible for protection under the Safe Harbor include all in-kind items, goods, and services that otherwise meet all applicable Safe Harbor conditions. The Safe Harbor does not provide protection for cash or cash equivalents remuneration, but it does not expressly prohibit gift cards. The OIG notes that vouchers for certain digital health tools and supports and limited-use gift cards that can be redeemed only for certain categories of items may be considered in-kind remuneration eligible for Safe Harbor protection. However, the OIG considers debit cards, rebate checks, and most gift cards to be cash equivalents and not protected forms of in-kind remuneration under the Safe Harbor. Waivers or reductions of cost-sharing amounts also are not protected by the Safe Harbor.

The Safe Harbor requires the in-kind digital health tool or support to have a direct connection to the coordination and management of care of the target patient population. The tool or support must be funded by a VBE participant that is a party to the applicable value-based arrangement, must be recommended by a patient's licensed health care professional, and may not be used to market other reimbursable items or services or to recruit patients. Further, a patient's insurance coverage cannot be considered when determining the availability of a tool or support; and the VBE must retain documentation sufficient to establish compliance for six years.

The Safe Harbor protects digital health technology tools or supports funded or furnished by manufacturers of devices and medical supplies—other than physician-owned distributorships—that are not VBE participants if the Safe Harbor's other requirements are satisfied. Thus, the Safe Harbor would permit a digital health company to partner with an FQHC to furnish a patient with digital health tools that facilitate remote patient monitoring, telehealth, two-way messaging, patient scheduling, appointment reminders, patient feedback, no-show outreach, patient payments, and other patient engagement tools.

OIG Advisory Opinion 20-08

On December 23, 2020, the OIG issued Advisory Opinion 20-08 (Advisory Opinion), addressing a proposal to use gift cards to incentivize patients to utilize health care services.

The arrangement's stated purpose was to improve eligible patients' attendance rate, a goal initiated after the FQHC's studies showed that 30 percent of its pediatric patients missed one or more preventive and early-intervention care appointments (Appointments). As proposed, the FQHC planned to offer a one-time $20 "big-box" store gift card to patients (or their parents or guardians) under the age of 19 who previously missed two or more scheduled Appointments within the past six months (Eligible Patients). To facilitate this program, the FQHC planned to contact Eligible Patients by phone and notify them of the opportunity to receive the gift card upon rescheduling and attending the Appointment, and to furnish the gift cards to Eligible Patients after their Appointments, upon verification of each patient's eligibility. During the Appointment—in addition to receiving necessary services—the FQHC planned to educate Eligible Patients regarding the importance of primary care and inform them of their options to facilitate attendance at future Appointments.

The FQHC indicated that gift cards would be offered to Eligible Patients regardless of health insurance status or ability to pay and that Eligible Patients would only be eligible to receive one $20 gift card over the course of the proposed arrangement. The Eligible Patient would have to attend a care Appointment and the FQHC would furnish the gift card to the Eligible Patient upon checkout after the Eligible Patient attended the appointment and an FQHC staff member verified the patient's eligibility. Eligible Patients or their parents or guardians would be given an option to choose one $20 gift card from four retailers. Eligibility to receive the gift card would not consider health insurance status or ability to pay for services, and the FQHC would not advertise the program, other than notifying Eligible Patients—or their parents or guardians—of the incentive by telephone. The FQHC further indicated that it would reevaluate the program on an annual basis to determine whether it was effective in improving the attendance rate for Eligible Patients. If the success rate of the program were to fall below 50 percent, the FQHC indicated that it would consider modifying or discontinuing the program.

The OIG Advisory Opinion Analysis

According to the OIG, the gift card incentive program proposed by the FQHC would implicate the Anti-Kickback Statute because the $20 gift card would constitute remuneration intended to influence Eligible Patients—at least some of whom would likely be Medicare or Medicaid program beneficiaries—to select the FQHC for future items or services (specifically, attending their rescheduled care appointments or seeking other federally reimbursable items or services from the FQHC in the future). The OIG opined that the gift cards would not be protected by the CMPL exception protecting incentives that promote access to care with a low risk of harm, or by the preventative care exception, because "one of the gift cards offered under the Proposed Arrangement would be to a retailer that is a big-box store, *i.e.*, it sells a wide variety of items …[and] such gift cards are not 'items or services' and are considered cash equivalents that are not protected by the exception."

However, the OIG concluded that the proposed arrangement would not constitute grounds for the imposition of administrative sanctions in light of the presence of the administrative safeguards outlined below.

Gift-Card Inducement Safeguards:

- *Small Pool of Existing Patients*. The pool of Eligible Patients is narrowly defined to include only those established patients who previously had two scheduled Appointments but missed them in the preceding six months. The OIG stated that the narrowly defined pool of Eligible Patients would minimize the risk of inappropriate patient steering because Eligible Patients would have established relationships with the FQHC by previously contacting it to schedule their Appointments.
- *No Increase in Cost to Federal Health Care Programs*. The gift card incentive would be unlikely to lead to increased costs to Medicare or Medicaid programs or patients through overutilization or inappropriate utilization because any increase in costs to federal health care programs resulting from Eligible Patients attending their rescheduled Appointments would reflect "appropriate" utilization.

- *No Harm to Competition*. The gift card incentive is unlikely to harm competition because: (1) an Eligible Patient could only receive the remuneration once even if they continued to miss appointments; (2) the remuneration would be of modest value ($20) even though the "big-box" type of gift card was a cash equivalent; and (3) outreach regarding the incentive program would only be to a narrowly defined group of Eligible Patients and not through public advertising.
- *Furthered Goal of Improvement in Patient Care*. The gift card incentive program is narrowly tailored and specifically targeted at improving attendance rates at Eligible Patients' care Appointments, as evidenced by: (1) the FQHC's reliance on internal data to identify a policy concern and potential solution; (2) the incentive program's focus on a targeted subset of patients to address the identified concern; (3) the FQHC's stated intention to pair the gift card offering with patient education, an eligibility verification process, documentation requirements, and an annual effectiveness review; and (4) the fact that the one-time reward for attending a care Appointment is not conditioned on utilization of the FQHC beyond the initial rescheduled Appointment.

OIG Advisory Opinion 12-21

In Advisory Opinion 12-21, the OIG concluded that an FQHC's offer of grocery store gift cards to capitated managed care patients would not constitute grounds for the imposition of sanctions under the AKS or CMPL. As part of its Medicaid program, the state in which the FQHC is located (State) engaged local managed care plans to provide services for reimbursement on a capitated basis. The FQHC was selected as a contracted provider by some of those managed care plans. Each managed care plan would assign its enrollees to specific contracted providers like the FQHC by reviewing factors such as the enrollees' geographic location and the contracted provider's available capacity. An enrollee would have to request reassignment to a different contracted provider if desired. If an enrollee failed to use the FQHC, the FQHC still would remain the enrollee's assigned provider, and the FQHC's payments would remain the same.

Under the Proposed Arrangement, the FQHC sent letters to capitated Medicaid managed care plan enrollees (regardless of health status) who either: (1) were newly assigned to the FQHC, or (2) were assigned to the FQHC at least one year prior but had not been seen by the FQHC (Eligible Enrollees). The letters, which were the only source of marketing, offered the Eligible Enrollee a gift card redeemable for $20 in groceries in exchange for a visit to the FQHC for a health screening or any other clinical service. The gift cards were presented to the Eligible Enrollee along with health educational materials and information regarding FQHC visits. Additionally, the Eligible Enrollee was limited to only one gift card in a 12-month period. The FQHC certified that the proposed arrangement is intended to: (1) encourage patients to be seen for care and to be engaged in preventative care; (2) encourage patients to learn more about the health center; and (3) help the health center achieve better health outcomes.

Although the OIG found that the gift card would constitute remuneration to federal health care program beneficiaries and would be of more than nominal value, it determined that the Proposed Arrangement would not constitute grounds for the imposition of CMPL penalties because the gift card was unlikely to influence beneficiaries to select the FQHC as their contracted provider. Beneficiaries were assigned to a provider based on neutral factors such as location, and they would have to affirmatively request a reassignment to the FQHC. Furthermore, the gift card was of "modest value" and could not be exchanged for cash. The OIG also noted that the gift card was not advertised to anyone other than certain beneficiaries already assigned to the FQHC.

The OIG also concluded that the Proposed Arrangement was of "minimal risk" of fraud and abuse under the AKS. The Proposed Arrangement would not result in increased costs to the federal health care programs, as the gift cards were offered only to Eligible Enrollees, and Medicaid would not change the capitated payments made to the managed care plans based on the nature or number of services that the FQHC provided to the Eligible Enrollees. Additionally, the gift card proposal was limited in marketing and the value of the gift card modest. The OIG noted that the FQHC's mission was to provide healthcare to a poor and underserved community and that the Proposed Arrangement would further benefit the population that the FQHC served by engaging them in their health care.

Compliance Best Practices

The new OIG guidance offers insight into how the OIG may distinguish FQHC patient incentives that constitute acceptable inducements to support care, from "suspect" incentives that offer FQHC patient inducements merely as an incentive for patients to obtain federally reimbursable items and services.

The fact that an FQHC patient incentive program does not fit within the confines of an AKS safe harbor does not mean that it necessarily violates the AKS. That compliance analysis is based on specific facts and circumstances. If the FQHC includes adequate safeguards contributing to a low risk of fraud and abuse in patient incentive arrangements, then such arrangements may pass AKS compliance scrutiny in the absence of safe harbor protection.

As noted in the December 2020 issue brief by the Center for Health Law and Policy Innovation of Harvard Law School, here are some common safeguards promoted by the OIG:

- **Not Inducement for Enrollment or Selection of FQHC as a Provider**: Eligibility for the patient incentive should not be tied to enrollment or selection of the FQHC as a provider for the patient. Arrangements that base eligibility in a manner that considers a person's past or anticipated use of a provider's health care services or conditioning of receipt of the incentive on a person agreeing to become a patient or agreeing to continue as a patient are considered "suspect" by the OIG.
- **No Cash or Cash Equivalents**: The OIG is more concerned about the provision of cash than it is with in-kind assistance. The use of a voucher system (e.g., food or transportation vouchers) is a common approach to structuring an in-kind arrangement.
- **Unadvertised**: The OIG generally prohibits public advertising for patient incentive programs. Screening patients for a need opens the door to informing eligible patients about related supports available to them without advertising the program.
- **Modest Value (Inexpensive Gifts or Services)**: OIG is more concerned about the provision of luxury items or services than it is about more modest forms.
- **Preventive Care Items or Services**: The OIG favors incentives to promote the delivery of preventive care items and services.
- **Written Policies and Procedures and Program Documentation**: Documenting the intent of the program, safeguards incorporated into it, how those safeguards are operationalized, and how adherence to the policies is monitored/ supported, helps demonstrate a commitment to minimizing the risk of noncompliance.

FQHCs should review and revise their patient incentive and gift policies to be consistent with the new OIG guidance. FQHCs should also consider monitoring and auditing patient incentive and gift programs as part of the annual compliance program work plans.

FQHCs considering new patient incentive or gift programs should consult with competent legal counsel to assist in: (1) structuring the program; (2) advising on the types of incentives or gifts that the FQHC can provide; and (3) ensuring that the program is protected by applicable AKS and CMPL exceptions or safe harbors.

Hinshaw health care law attorneys have significant experience in advising FQHCs and other health care organizations on licensure and federal qualification, nonprofit governance, federal grants and procurement law, Section 330 Public Health Service Act compliance, the Section 340B pharmacy discount program, mergers, acquisitions, joint ventures, affiliations, tax-exempt bond financing, tax-exempt organization regulation and policy, political activity and federal election campaign law, business transactions, general contracts and agreements, healthcare regulatory, fraud and abuse, data privacy and cyber security, reimbursement and operational issues.