

OIG approves gift cards to promote patient compliance with a preventive screening measure

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The U.S. Department of Health and Human Services Office of Inspector General (OIG) recently issued Advisory Opinion 23-03,¹ approving a proposal by the manufacturer of a colorectal cancer screening test and its wholly owned laboratory to provide gift cards to certain patients to encourage them to return the sample collection kits.

While limited in scope, this favorable opinion is noteworthy because OIG typically disfavors arrangements under which providers or suppliers distribute gift cards to incentivize patients to obtain federally reimbursable services. Although OIG approved the proposed arrangement at issue in Advisory Opinion 23-03, the agency also pointedly warned entities against structuring arrangements that differ from the facts of the proposed arrangement.

The arrangement

The requestors are the manufacturer of the first and only FDA-approved, non-invasive test for detecting signs of colorectal cancer and its wholly owned laboratory, which performs and processes the tests. The requestors certified that at least 30% of all patients who receive a test kit based on a physician's order do not return the kit to the laboratory for evaluation.

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Under the proposed arrangement, if the laboratory has not received a patient's test kit in a timely manner after at least two outreach attempts, the laboratory would send the patient a reminder letter informing the patient that they would receive a prepaid gift card of

up to \$75 if they return the kit by a specified deadline. The gift card would not be redeemable for cash and would not be reloadable after use.

The requestors would implement several safeguards to prevent fraud and abuse under the proposed arrangement, including:

- Mailing the gift cards only to those patients who return the kits by the deadline specified in the reminder letter.
- Advising patients that they may not use the gift cards on items or services provided by the requestors.
- Limiting patients to one gift card every 36 months, which is consistent with Medicare's coverage period for the screening test.
- Implementing processes to ensure patients who received a gift card during the 36-month period do not receive another one during that period.
- Refraining from patient-focused promotional activities that advertise the availability of the gift card.
- Prohibiting advertising or marketing the proposed arrangement to healthcare providers who may order the test.
- Excluding tests ordered by healthcare providers through the requestors' website from the proposed arrangement.

OIG's analysis

OIG concluded that the proposed arrangement would implicate both the Civil Monetary Penalty provision prohibiting inducements to beneficiaries (Beneficiary Inducements CMP) and the Anti-Kickback Statute because requestors would pay remuneration, in the form of a gift card, to beneficiaries to induce them to return the screening kit to the laboratory for processing.

Beneficiary inducements CMP

OIG first analyzed the proposed arrangement under the Beneficiary Inducements CMP, finding that it would satisfy the requirements of the exception to the definition of remuneration for incentives given to beneficiaries to promote the delivery of preventive care. The proposed arrangement would satisfy this exception because

the screening test is included in the U.S. Preventive Services Task Force's (USPSTF's) Guide to Clinical Preventive Services and is not directly or indirectly tied to the provision of other federally reimbursable services, and because the gift card is neither convertible to cash nor disproportionately large in relation to the preventive services.

Anti-Kickback Statute analysis

OIG next went on to analyze the proposed arrangement under the Anti-Kickback Statute. OIG began its analysis by distinguishing the Beneficiary Inducements CMP and the Anti-Kickback Statute, noting that its conclusion that the gift card does not constitute remuneration under the Beneficiary Inducements CMP does not automatically require it to draw the same conclusion under the Anti-Kickback Statute. Similarly, OIG noted that the fact that the proposed arrangement satisfies the preventive care exception to the Beneficiary Inducements CMP does not mean the proposed arrangement automatically is low risk under the Anti-Kickback Statute.

After taking care to distinguish the two statutes, OIG nevertheless concluded that the proposed arrangement would present a minimal risk of fraud and abuse for the following reasons:

- (1) **The proposed arrangement is unlikely to result in overutilization or inappropriately increase costs to federal healthcare programs.** The requestors would provide gift cards to patients only once every 36 months — a timeframe that complies with the USPSTF recommendation that all adults ages 45-75 receive the test every 1-3 years and Medicare's reimbursement of the test every 36 months. Further, requestors' inability to know which patients might receive gift cards protects against the risk that a provider may order the test in lieu of another procedure. Finally, the fact that the test is reimbursed at a set rate under Medicare's Clinical Laboratory Fee Schedule precludes requestors from directly or indirectly passing on the costs associated with the gift cards to federal healthcare programs.
- (2) **The proposed arrangement encourages patient compliance.** The proposed arrangement would promote patient compliance with a test recommended by the USPSTF and the American Cancer Society, and that the Centers for Medicare & Medicaid Services has said benefits patients and the Medicare program. The requestors would provide gift cards only to individuals who return the kit within the timeframe specified in the letter. The proposed arrangement therefore would promote compliance among patients who otherwise might not comply with a healthcare provider's order for the test.
- (3) **The proposed arrangement includes additional safeguards.** Several other safeguards lower the risk of fraud and abuse risk, including the fact that requestors would not advertise the proposed arrangement and would implement a process to ensure no patient receives more than one gift card in a 36-month period.

Key takeaways

OIG continues to issue advisory opinions and other guidance on the topic of gift cards, signaling that gift card programs remain a focus of both stakeholders and the government. Multiple significant and unique attributes contributed to the favorable result in this opinion, including the requestors' safeguards against overutilization and cost-shifting, the limited frequency of the remuneration, the benefits to patients and federal programs, and the proposed arrangements' inability to influence prescriber decision-making. Stakeholders should heed OIG's caution in the closing paragraph of its analysis that it "likely would reach a different conclusion" if any of the facts were different.

This opinion is noteworthy in several respects. First, when OIG addresses both the Anti-Kickback Statute and the Beneficiary Inducements CMP in an advisory opinion involving remuneration to beneficiaries it often relies on or parrots its risk analysis under the Beneficiary Inducements CMP as the rationale for concluding that the arrangement presents minimal risk under the Anti-Kickback Statute. In some cases, OIG's analysis of both statutes is intermingled.

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In Advisory Opinion 23-03, however, OIG reminded stakeholders that the statutes are different and that satisfying an exception to the Beneficiary Inducements CMP does not automatically protect an arrangement under the Anti-Kickback Statute. OIG reiterated this reminder in a series of recent FAQs.² Stakeholders should continue to consider the implications of an arrangement under both statutes.

Second, the proposed gift card program in Advisory Opinion 23-03 involved a pre-loaded credit card. Though OIG clarified that the gift card at issue in Advisory Opinion 23-03 was not an "instrument convertible to cash" for purposes of the preventive care exception, other pre-loaded, general use cards might fall within the broader category of "cash equivalents."

The distinction between an "instrument convertible to cash" and a "cash equivalent" — while perhaps lost on many outside of various financial sectors — is important when evaluating certain Beneficiary Inducements CMP exceptions and Anti-Kickback Statute safe harbors, which often prohibit the provision of "cash equivalents." Stakeholders should carefully evaluate the type and nature of gift card offerings against OIG's associated interpretations.

OIG's approach to concepts such as "in-kind" remuneration, "cash," and "cash equivalents," increasingly requires a careful analysis of

regulatory text, alerts, and advisory opinions. OIG recently issued an FAQ³ synthesizing some of its guidance on these concepts, clarifying that it considers gift cards to “big-box stores” for a particular item or a select category of items to be “in-kind” items but that unrestricted gift cards to “big-box stores” are not “in-kind” remuneration. In other guidance, OIG has clarified that unrestricted gift cards to “big-box stores” are considered cash equivalents.

Stakeholders interested in developing gift card programs should carefully consider OIG’s evolving position on this particular form of remuneration and keep in mind Advisory Opinion 23-03’s limited scope.

Notes

¹ <https://bit.ly/3Lrblk0>

² <https://bit.ly/3LWe9wj>

³ *Id.*

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