



## ALERTS

### HHS-OIG Declines Sanctions On Gift Card Incentive For At-Home Screening Kit Patients

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#### Highlights

U.S. Department of Health and Human Services addressed a lab test manufacturer's use of a gift card to encourage use of its at-home test

The agency determined the arrangement posed little risk of overutilization or increased costs to federal health programs because the gift cards would not be advertised or promoted

The opinion seems to demonstrate leniency by the agency when there is no risk of overutilization or increased costs to federal health programs

The Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG) issued [Advisory Opinion No. 23-03](#) on March 29 regarding a proposal related to the manufacturer's desire to issue a gift card to users of its product. The opinion addresses concerns about an at-home lab test manufacturer who wished to provide individuals a gift card for up to \$75 to encourage them to use and return the manufacturer's at-home colorectal cancer screening test.

Despite implicating both the beneficiary inducement civil monetary penalty

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(CMP) rules and the federal Anti-Kickback Statute (AKS), the agency determined it would not impose sanctions on the manufacturer.

The manufacturer has a proprietary, non-invasive colorectal cancer screening test that has been approved by the U.S. Food and Drug Administration (FDA). Medicare covers the test once every three years for Medicare beneficiaries aged 45 or older who meet certain criteria. Medicare reimburses the lab approximately \$500 per test. The U.S. Preventive Services Task Force (USPSTF) recommends adults ages 45 to 75 use the test once every three years. Additionally, the American Cancer Society recommends the test for individuals at average risk of developing colorectal cancer.

After a patient receives a prescription for the test, the lab ships the test sample collection kit to the patient's home. The patient collects their own stool sample and ships the kit back to the lab, which analyzes the stool sample for a result that may indicate the presence of colorectal cancer.

The manufacturer typically contacts a patient at the outset to request the timely return of the kit. If the lab does not receive the kit promptly, the manufacturer contacts the patient again. The manufacturer's data shows that more than 30 percent of patients fail to return their kit. For that reason, the manufacturer desires to provide patients a gift card to promote compliance with the kit return timeline.

Under the proposal, the manufacturer would send the patient one final reminder letter to return the kit. This letter would state that, if the patient returns the kit within a certain time frame, the manufacturer would send the patient a prepaid gift card for up to \$75. The manufacturer noted:

- The gift card would only be mailed to patients who return the kit by the deadline in the letter
- The gift card may not be used for items or services provided by the manufacturer
- Each patient would be limited to one gift card every 36 months, which aligns with Medicare's coverage for the test
- The manufacturer would have protocols in place to ensure each patient only received one gift card every 36 months
- Besides the letter, the manufacturer would not engage in any promotion of the gift card
- The manufacturer would not promote the gift card model to prescribers

## **Beneficiary Inducement CMP**

HHS-OIG determined the gift card model would implicate the beneficiary inducement CMP rules; however, since the proposal involves an incentive related to the promotion of preventive care services, it meets the Preventive Care Exception. Under the Preventive Care Exception, the gift card would be permissible because:

- The manufacturer would offer and provide the gift cards to individuals eligible for Medicare to promote a specific,

clinical service described in the USPSTF's Guide to Clinical Preventive Services

- The gift card would not be convertible to cash or be of a value disproportionately large in relationship to the value of the service
- The test would not be tied to the provision of any additional needed services

## Anti-Kickback Statute

HHS-OIG reached a slightly different conclusion as related to the Anti-Kickback Statute. Although HHS-OIG determined the gift card would likely be remuneration under AKS, the agency declined to impose sanctions because:

- The gift cards are unlikely to lead to improperly increased costs or overutilization of federally reimbursable services. Patients only receive the gift card once every 36 months, in line with Medicare's reimbursement and USPSTF's recommendation. The manufacturer would not promote or incentivize providers to engage in the program, so it is unlikely to influence a prescriber. And, the test is reimbursed by Medicare at a fixed rate, preventing the manufacturer from increasing the cost of the test and passing the cost of the gift cards on to the federal health care programs.
- The arrangement would promote patient compliance with a screening test that has been recommended by USPSTF and the American Cancer Society. Only patients among the 30 percent who do not return the kit would be eligible for the gift card, thereby promoting compliance with the prescription.
- The arrangement has several other safeguards that reduce the risk of fraud and abuse. For instance, the manufacturer will ensure that a patient only receives one gift card every 36 months and the manufacturer will not advertise the gift cards to patients or prescribers.

## Key Takeaways

HHS-OIG relied heavily on the public health benefits of the test to reach its conclusion. Colorectal cancer is the [third most commonly diagnosed cancer](#) in the United States and can often be [effectively treated if identified early with regular screenings](#). The manufacturer's test, which is non-invasive and completed at home, in conjunction with the gift card can encourage compliance with screening recommendations. This upstream prevention can help decrease cancer incidence and care costs down the line.

HHS-OIG also heavily emphasized the safeguards the manufacturer put in place. Providers considering a similar gift card model should consider implementing protocols that would limit how many patients are eligible, reduce duplication of gift cards, and avoid promotion or marketing of the model.

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