

## OIG Approves Cost-Sharing Waiver for Commercially Insured Patients

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**Bottom line:** The Office of Inspector General (OIG) has issued a favorable advisory opinion regarding a proposal by a manufacturer of a diagnostic test to waive cost-sharing for certain commercially insured patients. The OIG concluded that the arrangement does not violate the Federal anti-kickback statute or the Beneficiary Inducements CMP, given the specific safeguards in place. Key facts: The Requestor manufactures an FDA-approved, non-invasive colorectal cancer screening test. The proposal involves waiving cost-sharing for commercially insured patients who receive the test, which is not yet included in the U.S. Preventive Services Task Force (USPSTF) recommendations. The waiver applies uniformly to all eligible patients and is not linked to any other healthcare services or remuneration to prescribers.

**Agency analysis and reasoning:** The OIG determined that the Proposed Arrangement does not constitute prohibited remuneration under the Federal anti-kickback statute because it does not involve inducements for services reimbursable by Federal health care programs. The Beneficiary Inducements CMP is also not implicated, as the waiver does not influence Medicare or State health care program beneficiaries. Key safeguards include the absence of remuneration to prescribers and the fact that the waiver is limited to commercially insured patients. Additionally, the Requestor certified that Federal health care programs would not be billed as secondary payors, minimizing the risk of improper billing. The OIG noted that the arrangement does not present the typical risks associated with "carve-out" arrangements, as it does not disguise remuneration for Federal health care program business.

**Why this matters:** This advisory opinion provides a framework for structuring cost-sharing waivers in a manner that avoids implicating the Federal anti-kickback statute and Beneficiary Inducements CMP. Healthcare organizations considering similar arrangements should ensure robust safeguards are in place to prevent inducements related to Federal health care programs. OIG Advisory Opinions provide protection only for the facts and parties addressed in each opinion. However, this opinion may provide a framework for waiving cost-sharing payments for commercially insured patients if appropriate safeguards are implemented. A qualified health care attorney should be consulted prior to relying on the opinion when structuring a cost-sharing waiver.

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