

OIG Issues Favorable Advisory Opinion on Cost-Sharing Waivers for Commercially Insured Patients

Healthcare Law Update

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On January 13, 2026, the United States Department of Health and Human Services, Office of Inspector General (OIG) [issued](#) Advisory Opinion 26-01, approving a proposal by a manufacturer of a screening test for colorectal cancer to waive any cost-sharing obligations for commercially insured patients, concluding that the proposal would not violate the Federal Anti-Kickback Statute (AKS) or the Beneficiary Inducements Civil Monetary Penalty (CMP) provisions.

Although colorectal cancer screening tests are recommended by the U.S. Preventive Services Task Force (USPSTF), the manufacturer's specific test is not yet included in its recommendations. As a result, many commercial insurers impose cost-sharing on patients who receive the test, while similar tests included in the USPSTF recommendations are covered without cost-sharing. Under the proposed arrangement, the manufacturer would waive cost-sharing for all eligible commercially insured patients who receive the test and do not otherwise qualify for its financial assistance program. The waiver would apply uniformly and would not be tied to other healthcare items or services. The manufacturer certified it would not shift any related costs to Federal health care programs. The proposed arrangement would end once the USPSTF updates its recommendations to include the test.

The OIG determined that the proposed arrangement would not violate the AKS or implicate the CMP because it would involve no offer or transfer of remuneration to induce the purchase of items or services reimbursable by a Federal health care program or to influence Medicare or State health care program beneficiaries to select the manufacturer for such items or services. The OIG also emphasized that the manufacturer would not provide remuneration to ordering prescribers. The OIG noted that this

proposed arrangement differs from problematic arrangements that “carve-out” referrals of Federal health care program enrollees or business that disguise remuneration through the payment of amounts related to non-Federal health care program business.

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