

OIG Issues Favorable Opinion on Free Precision Oncology Reports

Fraud & Abuse

05.21.26

On May 20, HHS-OIG posted [Advisory Opinion 26-11](#) (Favorable), issued May 15, a favorable opinion addressing a precision oncology company's practice of providing consenting patients a free Supplemental Report expressing multi-cancer detection results in connection with an FDA-approved blood-based CRC screening test. The multi-cancer detection algorithm, which holds FDA Breakthrough Device designation, is run on the same blood sample collected for the CRC screening test and screens for 11 cancer types, 6 of which have no USPSTF-recommended screening modality. The algorithm is not yet FDA-approved as a standalone device and is not separately reimbursable. OIG analyzed the arrangement under both the Anti-Kickback Statute and the Beneficiary Inducements CMP, concluding that it generates prohibited remuneration under each, but that the risk of fraud and abuse was sufficiently low that OIG would not impose sanctions. No safe harbor applied, and the Preventive Care Exception was unavailable because neither test is listed in the USPSTF Guide. OIG credited three categories of low risk: (1) the arrangement is unlikely to cause overutilization, because the Supplemental Report requires no additional procedure, the underlying test is reimbursable only once every three years, the MCD Test is not itself reimbursable, and any follow up ; (2) it is unlikely to skew clinical decision-making, because physicians are not compensated for ordering or opting in, there is no targeted or direct-to-consumer marketing of the Supplemental Report, and the company actively monitors and removes third-party social media promotion; and (3) it is unlikely to cause steering or unfair competition, in part because the company's laboratory is the sole performer of the CRC screening test and 6 of the detected cancers lack any alternative screening option. The arrangement is time-limited, ending upon FDA approval or Medicare coverage of the MCD Test. The opinion offers a compliance framework for diagnostics companies seeking to deliver investigational, non-reimbursable test outputs to patients during the pre-approval period, but its favorable outcome is tightly tethered to the specific requester and facts presented.