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Competitive Market Analysis For Laboratory Management Decision Makers

What's Old Is New Again: Key Compliance Issues for Clinical Laboratories

Karen Lovitch

Laboratory Economics recently spoke with Karen Lovitch, Chair of health law and health care enforcement defense practices at Mintz Levin (Washington, D.C.) about top compliance challenges for clinical laboratories.

What have been the top compliance issues for clinical laboratories this past year?

What's old is new again. Dealing with discounts and waivers for out-of-network patients or patients whose care is not covered by a third-party payer remains a concern. Labs truly want the best for their patients – they want them to have access to testing, regardless of whether the patient's insurer pays for it. Labs often will adjust patient bills on an individual basis, and many have financial assistance programs. Labs are struggling with what is the most patient-friendly and compliance-friendly way to approach patient billing.

Depending on the source of payment, offering a discount to induce the patient to receive testing from the laboratory technically can implicate EKRA [the Eliminating Kickbacks in Recovery Act of 2018], the federal anti-kickback statute [AKS], or certain state laws, but implementing a reasonable, written financial assistance policy can lower the risk.

Collection of specimens also continues to be a challenge for labs that are not large enough to have a network of phlebotomists or patient service centers. Earlier this year there was an advisory opinion from the Health and Human Services Office of Inspector General (HHS OIG, 22-09, April 25, 2022) on paying draw fees to hospitals. A lab requested an opinion on whether it could pay contracted hospitals on a per-patient-encounter basis to collect, process and handle specimens that are then sent to the lab for testing. The lab would bill third-party payers, including federal health care programs, for testing. The OIG concluded that the proposed arrangement could implicate the AKS because it involved compensation paid by a laboratory to a party that could make or influence referrals to the laboratory for testing. The OIG is suspicious of any arrangement where a lab pays an actual or potential, direct or indirect referral source for specimen collection. Labs should proceed with caution when considering any arrangement involving payment for specimen collection fees.

I also should mention the telefraud arrangements that have received a lot of attention over the past few years. The Department of Justice has publicized many criminal enforcement actions involving laboratories that allegedly obtained fraudulent orders for laboratory testing through telemedicine visits, referred those orders to other unsuspecting laboratories for test performance, and then billed Medicare and other third-party payers for the testing. Reference laboratories therefore should consider whether they should check the background of referring laboratories and consider whether to include reference lab arrangements as part of their compliance work plan.

Are you still seeing a lot of fraud related to Covid testing?
Covid-19 testing fraud reports naturally have died down quite a bit recently, but an important court case related to Covid-19 testing fraud was resolved in 2022 when Mark Schena, President of Arrayit Corporation, was convicted of health care fraud.

However, private third-party payers continue to audit Covid-19 testing claims and are denying large swaths of testing based on lack of medical necessity. Generally, these claims relate to employer testing and school testing. In addition, some states, such as New York, required testing of nursing home employees and expected the commercial insurance companies to cover it, but some have refused to cover the testing, which left labs stuck in the middle. Labs need to know what the payer policies are now and need to abide by them. If Covid-19 testing isn't covered, labs should consider seeking payment up front.

What can new labs created during the pandemic do to minimize compliance risk?
Their situation is similar to many new labs or other businesses that focus first on business issues and do not always ramp up as quickly as they should with respect to compliance. Any lab interested in compliance program basics should start with the OIG's website, https://oig.hhs.gov/documents/compliance-guidance/806/cpglab.pdf.

What steps should all labs take right now to ensure they remain in compliance?
Every lab should have a person who has responsibility for legal and compliance matters even if the lab does not have a formal compliance program yet. Best compliance practices include appointing a compliance officer who oversees a compliance committee that meets regularly, implementing compliance policies and a training program, auditing and monitoring, allowing for anonymous reporting of compliance issues, not retaliating against those who report, following up on credible reports, and taking action against those who are non-compliant. Labs also should monitor guidance and other publications published by the Centers for Medicare and Medicaid Services, the Office of Inspector General for the Department of Health and Human Services, and other relevant state and federal agencies.