Legal and Regulatory Pitfalls for Laboratories and Ordering Providers: A Matter of Provider-Laboratory Collaboration and Risk

By Danielle H. Tangorre

Testing by clinical laboratories is governed by myriad federal and state statutes, regulations, and administrative guidance. Laboratories are required to be licensed under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In New York, laboratories meet CLIA requirements by receiving a valid New York State permit because New York was granted exempt status by the federal Centers for Medicare and Medicaid Services.[1] As such, laboratories that are located in or accept specimens from residents of the state of New York must hold a New York State Department of Health clinical laboratory permit.[2]

Laboratories that bill any federal health care program are also subject to the Anti-Kickback Statute, Stark Law, Eliminating Kickbacks in Recovery Act, Civil Monetary Penalties Law, False Claims Act, and the "substantially in excess rule."[3] New York also has a robust regulatory scheme that governs clinical laboratories and their relationships with ordering providers with regulations applicable to clinical laboratories and state-law counterparts of many of the federal rules.[4]

The Role of the Physician in the Laboratory Relationship

Independent laboratories and ordering providers have mutual responsibilities in the relationship. CLIA requires that a laboratory receive a written or electronic request from an authorized person, as determined by state law.[5] In New York, this requires an order by a licensed physician or other person authorized by law.[6] Under Medicare rules, the physician or qualified nonphysician practitioner must order medically necessary tests and document such medical necessity in the patient's medical record.[7] The laboratory must obtain a signed requisition or authenticated medical record documenting the ordering of particular tests and ensure that the documentation it receives from the ordering practitioner is accurate.[8]

Enforcement Actions Against Laboratories and Ordering Providers

The U.S. Department of Justice (DOJ) and the Office of the Inspector General at the U.S. Department of Health and Human Service (HHS-OIG) continue to pursue cases against laboratories and their owners, as well as related physicians, for improper relationships, payment of kickbacks, payment of

commissions to independent contractors, and medically unnecessary testing (among other issues).

Medical Necessity

Performing and billing for medically unnecessary testing continues to be a focus area by the HHS-OIG and DOJ. Medicare defines medical necessity as items or services "reasonable and necessary" for the diagnosis and treatment of illness or injury.[9] The government is often concerned about the physician-patient relationship, blanket orders/routine standing orders, requisition design, large panels, frequency of testing, bundling of tests, and whether the tests were used in the care plan and treatment of patients.

Laboratories cannot determine medical necessity of testing ordered and that decision lies within the purview of the ordering provider. As noted in the Model Compliance Plan for Laboratories, the HHS-OIG stated: "We recognize that laboratories do not and cannot treat patients or make medical necessity determinations."[10] While laboratories have a role as the billing entity, "a laboratory may rely on the ordering physician's determination of medical necessity in the laboratory's certification to HHS on the CMS-1500 form."[11] This tension was noted by the court in *U.S. ex rel. Groat v. Boston Heart,* 296 F. Supp. 3d 155 (D.D.C. Dec. 11, 2017) where the court noted the negotiated rulemaking and "tension between Medicare statutory medical necessity requirement . . . and the special circumstances related to laboratories."[12] As such, laboratories have no independent duty to determine medical necessity and can rely on the ordering provider but still must act to ensure only tests that are medically necessary are billed. As such, laboratories and ordering providers must work together to ensure medical necessity.

While laboratories can rely on certain medical determinations of the ordering provider, laboratories are not without responsibility. Laboratories still have a role in ensuring that they are billing for medically necessary tests which may extend to their design of the requisition, marketing materials, and other policies and procedures. For example, the owners of a Missouri laboratory agreed to settle allegations that it billed for upper respiratory infection and urinary tract infection tests that were not medically necessary allegedly due to a requisition form that prohibited ordering practitioners from making an independent medical necessity decision about the laboratory tests.[13]

Marketing

The DOJ and HHS-OIG have also recently focused on enforcing the Anti-Kickback Statute for alleged violations by which laboratories pay commissions to independent contractors for their marketing services on behalf of the laboratory. Over the last year, there has been a noticeable trend of enforcement in this area. Most recently, on February 28, 2024, the DOJ announced a guilty plea for the owner of a clinical laboratory for payment of commissions to independent contractor sales representatives that recommended medically unnecessary urine drug tests and respiratory pathogen panels.[14] The owner of the laboratory also entered into a civil settlement to resolve allegations related to the payment of commissions but also acknowledged that the sales representatives completed test requisitions using forged signatures and sham diagnosis codes.[15] The announcement also noted that several other individuals have pleaded guilty, including the marketers and the physician who ordered the testing.[16]

Other cases involve an announcement on January 10, 2024, by the DOJ that a now-defunct laboratory and its owner and chief executive officer agreed to collectively pay the United States and the state of New Jersey over $13 million and cooperate in DOJ's ongoing investigation.[17] On April 4, 2023, DOJ announced a settlement against a laboratory in Texas to resolve allegations that it paid commissions to independent contractor marketers and marketing firms that marketed on behalf of the laboratory.[18]

Telehealth

The DOJ has prosecuted numerous laboratories and their owners for allegedly violating the Anti-Kickback Statute by paying for patient referrals from providers working with telemedicine and telemarketing companies. HHS-OIG had enough cases and concern that it even issued a special fraud

alert in July 2022 concerning telemedicine companies using kickbacks to recruit and reward providers to order medically unnecessary medical services.[19]

In one notable case, the DOJ announced on December 21, 2023, that a nurse practitioner was sentenced to 20 years in prison after being found guilty of health care fraud by a federal jury in Miami.[20] The government alleged, and proved at trial, that the provider worked with telemedicine and marketing companies to sign orders for CGx and PGx testing, among other services, without pre-existing relationships with patients, without physically examining patients, and based solely on brief telephonic conversations with patients. Despite the lack of patient contact, the ordering provider signed certifications stating that she was the patients' treating provider and that the genetic tests she ordered were for the diagnosis and treatment of the patients' medical conditions. In exchange for these orders, the ordering provider was paid "consultation fees" and was provided referrals and the ability to bill Medicare for telemedicine visits for patient consultations.

Pass-Through Billing and Laboratory Hospital Relationships

Pass-through billing is yet another concern for providers, hospitals, and laboratories. In some situations, entities attempt to create relationships that run afoul of various rules, sometimes in order to attempt to gain a better reimbursement rate.

In an ongoing case that was initially announced on April 4, 2022, the DOJ filed a complaint under the False Claims Act against two laboratory CEOs, a hospital CEO, and other individuals and entities for violations of the Anti-Kickback Statute and Stark Law and improper relationships with various management service organizations.[21] The government alleged concerns related to processing and handling fees, waiving patient copays and deductibles, and improper consulting fees.[22] Former hospital executives entered into settlement agreements to resolve allegations relating to commissions to recruiters, and relationships with management services organizations.[23]

On February 9, 2024, the DOJ announced that the owner of a series of health care-related businesses and its co-defendant physician created a physician office laboratory and an independent clinical laboratory that used the same building and machines, and also created an independent laboratory in name-only in order to bill for the tests.[24]

Conclusion

Clinical laboratories and ordering providers have a mutual responsibility to ensure the appropriate ordering and testing of specimens by a clinical laboratory. Providers and laboratories alike must be mindful of the myriad federal and state laws that govern the testing of human specimens.

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Endnotes

1. 86 F.R. 16599 (Mar. 30, 2021).
2. N.Y. PHL § 574.
3. 42 U.S.C. § 1320a-7b; 42 U.S.C. § 1395nn; 18 U.S.C. § 220; 42 U.S.C. § 1320a-7a; 31 U.S.C. §§ 3729-3733; 42 C.F.R. § 1001.701.
4. N.Y. PHL Art. 5; 10 N.Y.C.R.R. Part 58 and 58-1; 10 N.Y.C.R.R. Part 34; N.Y. PHL § 238-a; False Claims Act N.Y.S. Fin. Law §187-194.
5. 42 C.F.R. § 493.1241(a).
6. 10 N.Y.C.R.R. § 58-1.7(b).
7. 42 C.F.R. § 410.32(a).
8. *Id.*
9. 1862(a)(1)(A) of the Act; 42 C.F.R. § 405.201(b).
10. Model Compliance Plan for Clinical Laboratories, *available at* https://oig.hhs.gov/documents/compliance-guidance/965/cpcl.html.
11. 296 F. Supp. 3d at 160-61.
12. *Id.* at 161-62.
13. Missouri Laboratory Owners Agree to Pay $1.9 million and Relinquish $7 Million in Escrow in Settlement of Civil Fraud Claims, U.S. Dep't of Justice (July 31, 2023), *available at* https://www.justice.gov/usao-edmo/pr/missouri-laboratory-owners-agree-pay-19-million-and-relinquish-7-million-escrow.
14. Georgia Laboratory Owner Pleads Guilty to Felony Charge and Pays $14.3 Million to Resolve Liability Relating to Kickbacks and Unnecessary Testing, U.S. Dep't of Justice (Feb. 28, 2024), *available at* https://www.justice.gov/opa/pr/georgia-laboratory-owner-pleads-guilty-felony-charge-and-pays-143-million-resolve-liability.
15. *Id.*
16. *Id.*
17. New Jersey Laboratory and Its Owner and CEO Agree to Pay Over $13 Million to Settle Allegations of Kickbacks and Unnecessary Testing, U.S. Dep't of Justice (Jan. 10, 2024), *available at* https://www.justice.gov/opa/pr/new-jersey-laboratory-and-its-owner-and-ceo-agree-pay-over-13-million-settle-allegations.

18. Texas Laboratory Agrees to Pay $5.9 Million to Settle Allegations of Kickbacks to Third Party Marketers and Unnecessary Drug Tests, (Apr. 4, 2023), *available at* https://www.justice.gov/opa/pr/texas-laboratory-agrees-pay-59-million-settle-allegations-kickbacks-third-party-marketers-and.
19. Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies, Office of Inspector General (July 20, 2022), *available at* https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf.
20. Nurse Practitioner Sentenced for $192M Medicare Fraud Scheme, U.S. Dep't of Justice (Dec. 21, 2023), *available at* https://www.justice.gov/opa/pr/nurse-practitioner-sentenced-192m-medicare-fraud-scheme.
21. Justice Department Files False Claims Act Complaint Against Two Laboratory CEOs, One Hospital CEO and Others Across Texas, New York, and Pennsylvania, U.S. Dep't of Justice (Apr. 4, 2022), *available at* https://www.justice.gov/opa/pr/justice-department-files-false-claims-act-complaint-against-two-laboratory-ceos-one-hospital.
22. *Id.*
23. Hospital Executive and Three Texas Physicians to Pay Over $880,000 to Settle Kickback Allegations Involving Laboratory Testing, U.S. Dep't of Justice (Dec. 4, 2023), *available at* https://www.justice.gov/opa/pr/hospital-executive-and-three-texas-physicians-pay-over-880000-settle-kickback-allegations.
24. Testing Laboratory Co-owner Admits $3.8 Million in Fraudulent Billing, U.S. Dep't of Justice (Feb. 9, 2024), *available at* https://www.justice.gov/usao-edmo/pr/testing-laboratory-co-owner-admits-38-million-fraudulent-billing.