LIGHTHOUSE
Lab Services

Supplementary Topics in Laboratory Compliance

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Making Quality Lab Testing More Accessible

Supplementary Topics in Laboratory Compliance

Below is a summary of certain areas of attention that all clinical laboratories should keep in mind. This information is being provided as a courtesy and is not and should not be construed as compliance or legal advice. This list is not all-inclusive but may be considered as a starting point for Clients' compliance programs.

The HHS-OIG expects entities to have active compliance programs that are tailored to detect misconduct likely to occur within that particular line of business. Clinical laboratories should look to the 1998 Compliance Program Guidance for Clinical Laboratories for an initial set of requirements for the compliance plan.[1] Every clinical laboratory should ensure that the laboratory has (i) developed standards of conduct, (ii) designated a compliance officer, (iii) provided access to the compliance officer, including anonymous reporting, and (iv) established an active education and training program, among others. Laboratories should be aware of relevant fraud and abuse laws, including Stark, HIPAA, the Anti-Kickback Statute and the Eliminating Kickbacks in Recovery Act, as well as state law counterparts. It is also imperative that an entity engages in active risk identification and mitigation. With an ever-changing landscape for clinical laboratories, this requires active involvement by all stakeholders.

Clinical laboratories should look to the DOJ Criminal Fraud Section 2020 Guidance to assess the effectiveness of their corporate compliance program.[2] Common questions that DOJ asks during an investigation are: (1) "is the corporation's compliance program well designed"; (2) "is the program being applied earnestly and in good faith"; and (3) "does the corporation's compliance program work in practice?".[3] For policies and procedures, the OIG looks to the design, comprehensiveness, accessibility, integration, training and communication.[4] One of the most fundamental aspects is whether the compliance program actively addresses the key regulatory obligations and risks facing that particular entity.

Ordering of Tests

Requisition Design

Laboratories should be mindful in how they design their laboratory requisition. Laboratories should ensure that the requisition design promotes compliant ordering and captures all required information. The form should promote the ordering provider to individually determine medical necessity and to limit standing orders. Requisitions should allow the ordering provider to include diagnosis information for all tests ordered.

Standing Orders

Standing orders have been a cause for concern for decades. The OIG views standing orders as an area of potential for fraud and abuse and encouraging testing that are not medically necessary. Standing orders

[1] https://oig.hhs.gov/authorities/docs/cpglab.pdf
[2] Dept. of Justice, Criminal Division, Fraud Section, "Evaluation of Corporate Compliance Programs" (updated June 2020) *available at* https://www.justice.gov/criminal-fraud/page/file/937501/download
[3] *Id*.
[4] *Id*. At 3.

may be appropriate for individual patients with an extended course of treatment but should not be a default for providers or used for a provider for all patients across a practice. A laboratory should ensure that there are policies in place to assess the use of such orders, ensure that there is a fixed term, and review periodically. The OIG has also firmly stated that standing orders alone are not sufficient to demonstrate medical necessity.

Reflex and Confirmation Testing

Laboratories should carefully consider offering reflex and confirmation testing. Reflex and confirmation testing can be an area of concern because it can result in the laboratory performing medically unnecessary testing. The requisition should delineate circumstances where reflex or confirmation testing is appropriate but not have it as a default for the ordering provider. Laboratories should ensure that they always offer the ordering provider the ability to order a test without reflex or confirmation testing.

Ordering Practitioner Signature

Most commercial insurers default to the Medicare rule regarding signatures on requisitions. Historically, signatures were not required but Medicare has recently changed the rules. The laboratory should ensure that they have a policy that firmly addresses signature and documentation requirements in accordance with the current rules.[5]

Customized Profiles

The OIG also has historical concerns regarding customized profiles. Customized profiles can be used but the laboratory has an obligation to provide an annual notice that explains the reimbursement for each component of profile, and to understand that it may result in tests that are not covered, as well as to understand the legal risks, including the potential for false claims, for knowingly submitting a claim that is not reasonable or necessary. This is an area of concern such as evidenced by the DOJ settling a False Claims Act case with a laboratory for $256 million due to the use of custom profiles and standing orders that were not medically necessary.[6]

Billing of Tests & Collection of Fees

Overall, laboratories should ensure that all claims for testing submitted identify the services to be billed, are billed appropriately, identify the relevant parties and do not offer inducements for medically unnecessary testing. In addition, while laboratories are not in a position to determine medical necessity, laboratories still have an obligation to ensure that the tests for which they bill have documentation to support medical necessity.

[5] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/LabServices-ICN909221-Text-Only.pdf

[6] U.S. Attorney's Office, Dist. of Massachusetts, *Millennium Laboratories to Pay $256 Million to Resolve False Billing and Kickback Claims* (Oct. 19, 2015), *available at* https://www.justice.gov/usao-ma/pr/millennium-laboratories-pay-256-million-resolve-false-billing-and-kickback-claims

Medical Necessity

All claims being submitted to a state or federal funded health care programs, as well as commercial payors, must be for services that are medically necessary and reasonable. The submission of claims for services that are not medically necessary can result in false claims as well as other legal actions. Such claims can also be subject to audit and recoupment. It is important to ensure that all testing orders are accompanied by an appropriate health care provider order and test requisition form. Test requisition forms require physicians to think about the medical necessity of the test that they are ordering. It is also recommended that physicians send documentation of medical necessity from chart notes. Particular areas of scrutiny for medical necessity are custom profiles, automated profiles, and standing orders.

Pass-Through Billing

Pass-through billing is when a hospital or laboratory pays another laboratory to perform their testing and then bills the claims to the insurer as though the hospital or non-testing laboratory performed the test themselves, without referencing the laboratory that actually performed the tests. This prohibited billing structure is often used to work around the lack of contractual relationships the outsourced laboratory has with payers as well as to avoid scrutiny of the laboratory. Healthcare facilities can have compliant pass-through billing relationships with laboratories that take into account the variety of regulatory laws, but not under the circumstances described above.

Tests Performed by Others

In addition to the scenario of pass-through billing, laboratories have to be mindful and have policies and procedures in place to address reference arrangements and other such arrangements when another entity is involved. Most particularly, laboratories must be mindful of the 70/30 rule under Medicare. A referring laboratory can refer work to an outside laboratory and either (i) have the outside laboratory bill for the work it perform or (ii) bill the work itself. In the latter instance, however, the referring laboratory can only bill for the work that it did not perform if overall it does 70 percent of its work on site. Violations of the 70/30 rule can result in double billing and other charges related to false and fraudulent billing.

Waiver of Fees, Co-Payment, and/or Deductibles

The routine waiver of fees, co-payment, and/or deductibles is a considerable area of risk for laboratories and could be considered health care fraud. Under certain circumstances, waiver of a co-payment or a deductible can be permissible if it is not offered as a part of an advertisement, it is not routinely done, and a good faith determination of need is made. The laboratory must have policies and procedures in place to address this complex area.

Financial Assistance Policies

Financial assistance can also be provided in some circumstances where a patient demonstrates financial hardship. It is important to have a Financial Hardship Policy and Procedure in place to follow, a Certification of Financial Need of Account for the patient to fill out with relevant and necessary information to assess such financial hardship, and a Financial Assistance Letter to provide to the patient.

Unbundling

Unbundling occurs when each laboratory test in a panel or certain related tests that should be billed together, are billed separately with separate CPT codes rather than billing them together as a bundle with one CPT code. While this may lead to higher reimbursement for a laboratory, it also raises concerns of fraud and abuse. Unbundling can result in false claims as well as other legal actions. Unbundling was raised as a particular area of concern in the review done by CMS Healthcare Fraud Prevention Partnership in 2018.[7]

Documentation for Audits

Laboratories should always ensure that they retain the appropriate documentation to support the testing being performed, in case of an audit. This has become true more so now than ever, as audits are expected to occur due to the COVID-19 pandemic. Tests should be supported by an appropriate health care provider order and test requisition form. Such documentation should support the medical necessity of the testing being performed. It is also recommended that laboratories obtain from the ordering healthcare provider documentation of medical necessity from chart notes. Maintaining the appropriate documentation can help to avoid a situation where a laboratory is responsible for an overpayment, accused of billing false claims, as well as avoiding other legal actions.

Advanced Beneficiary Notices

ABNs are used to notify patients that an ordered service may not be reimbursable and allow the patient to decide whether to receive the service and pay or not receive the service. Since the laboratory rarely engages with the patient directly, it is important the laboratory have policies and procedures in place to appropriately train the ordering provider and to ensure that ABNs are used appropriately and without duress or coercion. The OIG has also expressed that routine notices to beneficiaries that merely state the potential for a denial of payment are not acceptable and that a laboratory may face sanctions for failure to appropriately and adequately notify the patient.[8]

Coding

Laboratories must be mindful of using the appropriate codes as the amount of payments for a tests is dependent on the CPT code. The laboratory should be mindful of national coverage decisions and medical coverage policies, and even if the laboratory chooses to outsource its billing to a vendor, the laboratory is still ultimately responsible.

Sales and Marketing

Overall, laboratories should ensure that sales and marketing staff are not engaging in deceptive practices to generate business nor engaging in conduct that raises other areas of concern, such as testing that is not medically necessary.

[7] Examining Clinical Laboratory Services, A Review by the Healthcare Fraud Prevention Partnership (May 2018), *available at* https://www.cms.gov/files/document/download-clinical-laboratory-services-white-paper.pdf

[8] Medicare Claims Processing Manual, ch. 30, §50.1-50.2, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf

Payment Structures

Payment structures of sales and marketing is one of the area's most fraught with regulatory concern. Generally, sales and marketing personnel should not be paid based on the volume or the value of the business that they bring in. This type of structure can be problematic under the Eliminating Kickback in Recovery Act (18 U.S.C. § 220) which does not provide for a Bona Fide Employee exception as the Anti-Kickback Statute does. Sales and Marketing personnel can be paid a base salary that is consistent with fair market value for the services rendered and does not in any manner take into account (directly or indirectly) the volume or value of any patient referrals by either party. Sales and marketing personnel can be reviewed for salary increases based on their qualifications and experience. Additional compensation in the form of a bonus can be provided to sales and marketing personnel based on different performance metrics such as overall teamwork, adherence to the compliance plan, and commitment to the job.

Notes on Other Specific Areas of Focus

Placing Phlebotomists in Offices

Independent laboratories should be aware of the compliance concerns when asked to place phlebotomists in the office of an ordering provider. Placement of a phlebotomists in an office implicates the Anti-Kickback Statute. The OIG has made clear that the phlebotomists cannot perform additional tasks that are the responsibility of the physician's office staff, including but not limited to taking vital signs, calling patients with results, or performing clerical services. In addition, some states have prohibited this practice.

Routine Screening Testing and Pooled Testing for COVID-19

Testing, when performed for screening purposes, including pooled testing, is not required by federal law to be covered by insurers, although some insurers have opted to cover it and such payor policy will need to be reviewed on a case by case basis. In such instances where testing for screening purposes is not covered, payment should be sought directly from the entity or individual that testing is being performed for (i.e. employer, school). Screening testing is often performed on asymptomatic individuals or individuals of which there is no reason to suspect infection. The purpose of screening testing is early detection.

Cancer Genomic Testing (CGx) and Pharmacogenetic Testing (PGx)

CGx testing is performed in an effort to find genetic mutations that may indicate that an individual is at a higher risk of developing certain cancers. PGx testing is performed to help determine how effective a medication may be for a particular individual. Both CGx and PGx testing are heavily scrutinized for fraud and abuse. Some common scenarios that may provide cause for concern are marketers going door to door collecting DNA swabs for genetic testing, DNA swabs being collected at health fairs for genetic testing and targeting of the elderly for DNA swabs for genetic testing. Fraud and abuse issues may present when marketers are receiving kickbacks for each DNA swab they collect or in the case of genetic testing when issues of medical necessity arise. Insurers such as Medicare, have often taken the stance that unless such testing is performed for the diagnosis or treatment of an illness or injury or for the

purpose of improving the functioning of a malformed body member, such testing will not be covered and will be considered not medically necessary.

Toxicology

Toxicology laboratories have faced increased scrutiny over the last few years. Areas of concern include (i) giving supplies to customers, (ii) using large panels and (iii) "excessive" urine testing. With respect to supplies, the government has stated that the provision of free POCT cups (with embedded immunoassay testing strips) to physicians violates Stark and the AKS.[9] Many payors have limited the number per month or per year of definitive testing and also have limits or discourage the use of large panels. There has been an increase in cases and settlements related to laboratories that submitted presumptive and definitive UDT which the government or payors allege are not medically necessary. Laboratories should carefully monitor and assess the types and quantities of tests they are running and review such billing practices in accordance with payor policies.

2014 Special Fraud Alert

In 2014, the OIG issued a special fraud alert to address a few arrangements that the OIG saw as problematic, including (1) arrangements whereby clinical laboratories were paying or otherwise compensating physicians and ordering providers to collect, process and package patients' specimens and (2) registry payments.[10] Registry payments involved arrangements whereby laboratories were coordinating or maintaining databases of data on patients who had certain tests performed and paying physicians or providing physicians with other benefits to supply such data. Clinical laboratories should be aware of this special fraud alert and aware of the concerns from the OIG.

CLIA

Laboratories should be mindful that the laboratory is following all rules under state and federal law that govern the licensure of clinical laboratories and testing, including the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). The CLIA program, and its state counterparts, regulate laboratories to ensure that the laboratory is providing accurate and reliable test results. Laboratories should be aware that there are a few CLIA condition-level citations that may be flagged during routine inspections. These categories include non-enrollment in proficiency testing, proficiency testing referrals, and certain violations of personnel qualifications.

Authorized Ordering of Tests

In order to perform a test, laboratories must have a written or electronic request by an authorized person, meaning an individual authorized under state law.[11] This generally means that certain professionals must order the test, but under some state laws this may mean that an individual can order the test. Laboratories should carefully review state law to determine when direct-to-consumer testing is

[9] DOJ amicus brief in Ameritox, Ltd. V. Millennium Laboratories Inc., *available at* https://assets.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2016/P13handout4.pdf

[10] Special Fraud Alert: Laboratory Payments to Referring Physicians, *available at* https://oig.hhs.gov/documents/special-fraud-alerts/866/OIG_SFA_Laboratory_Payments_06252014.pdf (June 2014)

[11] 42 C.F.R. § 493.1241(a).

authorized and to only accept orders from authorized individuals. The relationship between the laboratory and the authorized individual is an area of scrutiny and may have implications under the Anti-Kickback Statute or its state counterparts.

Personnel

CLIA and state law regulate the qualifications, including the educational background, training and experience, of the personnel who are directing, supervising and performing procedures at the laboratory. Laboratories should ensure that all required positions for the complexity level of the laboratory are filled and that such individuals meet not only the qualifications set forth by CLIA but also by state law. It is the laboratory's responsibility to review and ensure that such individuals have all proper qualifications.

Proficiency Testing

CLIA requires that laboratories performing moderate and high-complexity testing enroll in an approved proficiency testing program for verification of each specialty, subspecialty and analyte for which the laboratory is certified. CLIA uses this program to verify the accuracy and reliability of the testing being performed by the laboratory. Proficiency testing samples must be tested in the same manner that the laboratory tests patient specimens and failure to pass the proficiency testing can result in technical assistance or a more serious sanction, including prohibition on testing for the unsuccessful analyte, subspecialty or specialty.[12]

The other main area of concern surrounding proficiency testing is to ensure that there are no improper referrals, and that no discussion occurs regarding proficiency testing results with another laboratory before the event cut-off date.[13] Effective as of May 2014, there is a specific framework for sanctions for proficiency testing referral cases based on the extent and severity of the violation.

[12] 42 C.F.R. §§ 493.801-493.803.
[13] 42 C.F.R. § 493.801(b).