Annual Notice to Ordering Providers-2025

Dear Provider:

Med-Lake Laboratory (Med-Lake) maintains an active compliance program based on the guidelines set forth by the Office of Inspector General (OIG) of the United States Department of Health and Human Services. The OIG suggests that independent clinical laboratories publish an annual notice to its referral sources regarding laboratory test orders and fee schedules. The following information is intended to promote awareness of federal regulations and to explain the requirement for providers to furnish appropriate documentation when ordering testing services. Please review this material carefully and contact your Med-Lake Sales Representative or Compliance Officer, with any questions you may have.

There are four high risk areas that physicians and their employees should be familiar with: coding and billing; reasonable and necessary services; documentation; and improper inducements, kickbacks and self-referrals.

Coding and Billing

A diagnostic laboratory test is considered a laboratory service for billing purposes, regardless of whether it is performed in:

- A physician's office, by an independent laboratory;
- By a hospital laboratory for its outpatients or nonpatients;
- In a rural health clinic; or
- In an HMO or Health Care Prepayment Plan (HCPP) for a patient who is not a member.

Laboratory services furnished by an independent laboratory are covered under SMI if the laboratory is an approved Independent Clinical Laboratory. However, as is the case of all diagnostic services, to be covered these services must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. A small number of laboratory tests can be covered as a preventive screening service.

The CMS adjusts the fee schedule amounts annually to reflect changes in the Consumer Price Index for all urban consumers (CPI-U) (U.S. city average) and the 10-year moving average of changes in annual economywide private nonfarm business multi-factor productivity, unless alternative updates are specified by legislation. The CMS communicates this information via an annual recurring update notification (RUN). The CMS also determines, publishes for A/B MAC (A) or (B) use, and places on its web site, coding and pricing changes. This information is updated on an annual basis.

All test orders must be accompanied by diagnostic information (diagnosis codes and related items) demonstrating the medical necessity for the laboratory test, and Med-Lake:

- May only submit diagnostic information obtained from the ordering practitioner,
- May not supply these diagnostic codes for you, and
- May not copy diagnostic codes from earlier tests.

Clinical care guidelines and coverage and reimbursement policies make clear that the practitioner:

- Should not submit standard diagnostic codes along with customized test panels and standing orders; and
- Should select diagnosis codes based on the individual circumstances of each patient's case, choosing the diagnosis code that matches the most specific clinical/medical reason for the testing ordered.

Med-Lake will contact the ordering practitioner if diagnostic information is missing from test order forms. We remind you that "blanket" and "standing orders" are generally not permitted. All orders should be based on personalized care for each patient.

Medical Necessity

According to CMS, medically necessary services or supplies contain the following:

- Are proper and needed for the diagnosis or treatment of your medical condition.
- Are provided for the diagnosis, direct care, and treatment of your medical condition.
- Meet the standards of good medical practice in the local area and are not mainly for the convenience of you or your doctor.

Medicare publishes National and Local Coverage Determinations (NCDs and LCDs) setting forth coverage and reimbursement criteria for the various types of clinical laboratory testing. Many commercial payors have similar medical necessity policies, setting forth clinical care guidance and requirements for coverage and reimbursement of various laboratory testing services, including genetic/molecular and toxicology testing. Med-Lake's Annual Notice is designed to cover laboratory testing ordered for beneficiaries covered by commercial or government health plans.

If a physician requests an independent laboratory to obtain specimens in situations which do not meet, or without regard to whether they meet, the medical necessity criteria in Chapter 15 of the Medicare Benefit Policy Manual, an educational contact with the prescribing physician is warranted and, where necessary, corroborating documentation should be obtained on claims until the A/B MAC (B) is assured that the physician prescribes such services only when the criteria are met.

Documentation

MEDICARE SIGNATURE REQUIREMENTS

- Unsigned physician orders or unsigned requisitions alone don't support physician intent to order.
- Physicians should sign all orders for diagnostic services to avoid potential denials.
- If the signature is missing on a progress note, which supports intent, the ordering physician must complete an attestation statement and submit it with the response. For an example of a signature attestation statement, visit the CERT Provider website. If the signature is illegible, an attestation statement or signature log is acceptable.
- Attestation statements are unacceptable for unsigned physician orders or requisitions.

- Documentation in the patient's medical record must support the medical necessity for ordering the service(s) per Medicare regulations and applicable Local Coverage Determinations (LCDs). Submit these medical records if they're requested.

These records need to be available to submit upon request:

- Progress notes or office notes
- Physician order or intent to order
- Laboratory results
- Attestation or signature log for illegible signatures

In addition to physician signature, Med-Lake requires patient demographic information, date of collection, and all tests clearly marked.

The Anti-Kickback Statute

The Anti-Kickback Statute is a federal criminal law that prohibits healthcare providers from receiving kickbacks or referring patients to services in exchange for remuneration, which is money paid for work or a service. In a laboratory setting, a phlebotomist performing clerical or medical functions not directly related to the co lection or processing of laboratory specimens can be seen as a violation of the anti-kickback statute. This includes checking in patients, cleaning office rooms, obtaining vitals, testing for the physician's office laboratory, or performing any clerical services. Providing offices with anything of value, such as office and medical supplies used by staff other than the laboratory phlebotomist can also be seen as a kickback. Med Lake Laboratory follows all OIG requirements and all federal laws. Mandatory Anti-kickback Statute training is provided to all staff yearly, but any questions or concerns can be submitted via email to our compliance officer at lwilkinson@medlakelab.com as needed.

Sincerely,

Lisa Wilkinson

Administrative Director/Compliance Officer