ALVERNO LABORATORIES

January 2026

Dear Physician,

As part of Alverno Laboratories' Compliance and Quality Management Program—and in accordance with Medicare, CLIA, CAP, and ISO 15189 requirements—we provide this annual reminder outlining key responsibilities related to laboratory test ordering and medical necessity documentation. This notice serves as regulatory compliance education and supports our shared commitment to high-quality, compliant patient care.

Medical Necessity & Diagnosis Documentation

- **Responsibility for medical necessity documentation:** You, the ordering physician, and the laboratory are responsible for ensuring that appropriate diagnostic information is provided for each test ordered on the laboratory requisition to support medical necessity, in accordance with the Balanced Budget Act of 1997 (Pub. 105-3, effective January 1998).
- **Required format:** This documentation must be reported using a valid ICD-10-CM diagnosis code.
- **Chemistry panels:** All components of Medicare-approved Chemistry Panels must also meet Medicare Medical Necessity guidelines.
- **Medical record requirement:** Diagnostic information must be documented in the patient's medical record for each date of service in order for Medicare to reimburse the testing.

National & Local Coverage Determinations (NCDs/LCDs)

- **Coverage determinations:** Some laboratory tests are subject to published National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs), which specify the ICD-10-CM diagnosis codes that Medicare will cover.
- **When an ABN is required:** If there is reason to believe that Medicare will not reimburse a test (for example, the patient's condition is not covered under the applicable NCD or LCD), the physician must have the patient sign an Advance Beneficiary Notice of Non-Coverage (ABN) before specimen collection.
- **Prohibition of blanket ABNs:** It is against Medicare regulations to require all Medicare patients to sign an ABN (i.e., a "blanket ABN").

Private Payer Medical Necessity & Prior Authorization

- **Private insurance policies:** Some private insurance carriers maintain their own Medical Necessity policies and will not reimburse for tests that do not meet those requirements.
- **Physician responsibility:** In these cases, you, the physician, are responsible for providing an ICD-10-CM diagnosis code that meets the payer's Medical Necessity criteria.
- **Prior authorization:** Any required prior authorization must be obtained by the physician's office before services are performed.

Documentation Retention & Audit Cooperation

- Medical record documentation must be maintained and made available upon request.
- Cooperation with audits and inspections is required under CMS, CAP, CLIA, and ISO standards.

Fraud, Abuse & Inducement Prohibitions

- **No free services:** The laboratory is not permitted to provide free services to any individual.
- **Prohibition on write-offs and "perks":** Write-offs due to missing or incomplete billing information, professional courtesy requests, or other "perks" may be viewed by the Office of Inspector General (OIG) as improper inducements from the laboratory to the physician. These practices may subject both parties to scrutiny for potential fraud and abuse.
- **No inducements for referrals:** Free or discounted services intended to influence or reward referrals are strictly prohibited.
- **Regulatory risk:** Such practices may raise concerns under the Federal Anti-Kickback Statute and the Stark Law.

PECOS Enrollment Accuracy

- **Use of PECOS:** Medicare strongly encourages all providers to use the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) system when revalidating enrollment information, adding a reassignment of benefits, or enrolling in Medicare as a new provider.
- **Important note:** The provider name used in PECOS must match exactly the provider name on file in the NPI system.

While we are obligated to communicate and enforce Medicare regulatory requirements, we recognize that these regulations can at times present operational challenges for providers, patients, and the laboratory. By working collaboratively and in alignment with these requirements, we can help ensure regulatory compliance, minimize disruptions, support appropriate patient testing, and facilitate proper Medicare reimbursement for laboratory services.

If you have any questions regarding the application of the above policies, please contact the Alverno Laboratories Compliance Department at **ACOCOMPLIANCETEAM@alvernolabs.com** or Alverno Billing Services at **877-937-2190**.

Sincerely,

Don Lair, MBA, MLS(ASCP)^{CM}, LSSGB
Alverno Compliance Officer