

2025 Annual Physician Notice

Dear Physician:

The Office of Inspector General (OIG) recommends clinical laboratories send notices to physicians and other providers who use their services, at least once a year, to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation. The following information is intended to promote awareness of federal regulations and to explain the requirement for physicians to furnish appropriate documentation when ordering testing services. If you have questions about the contents in this notice, we encourage you to contact us for more information.

MEDICAL NECESSITY:

Medicare will only pay for tests that meet the Medicare coverage criteria and are medically necessary for the diagnosis or treatment of the individual patient. It is the responsibility of the healthcare provider to document each test ordered and the corresponding diagnosis information in the patient's medical record. Diagnosis codes are required on the test requisition form to support the medical necessity of each test ordered. As a participating provider in the Medicare Program, Prometheus has a responsibility to educate physicians and to implement ordering procedures to ensure all test requested are performed and billed in a manner consistent with all federal/state laws and regulations. As the physician, you are responsible for ordering tests only when they are medically necessary, for documenting medical necessity in the patient's permanent medical record, and for providing the appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Prometheus. Our paper requisitions are designed to assist providers in meeting documentation requirements regarding medical necessity of laboratory testing. It should only supplement, not replace, other forms of documentation and notes used by you. ***The OIG takes the position that physicians or other ordering providers authorized by law to order clinical laboratory tests, who knowingly cause a false claim to be submitted to any federally funded program, may be subject to sanctions or remedies available under civil, criminal and administrative law, such as the False Claims Act.***

PRIOR AUTHORIZATION:

Certain lab tests may require pre-authorization according to the patient's insurance provider's guidelines. Any required pre-authorization paperwork should be completed by the ordering provider's office before the lab test order is submitted. Please include the pre-authorization paperwork with the lab requisition form, when applicable, along with any related documentation. If the laboratory determines that pre-authorization is needed, and there is not enough information included on the patient paperwork to obtain it, we will contact the ordering physician's office before testing and request more clinical information for this purpose.

MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS:

Prometheus is subject to Medicare national coverage determinations (NCD) and local coverage determinations (LCD) of the Part B Medicare Administrative Contractor (MAC) for Jurisdiction E, Noridian Healthcare Solutions. Additional information can be obtained online at:

<https://med.noridianmedicare.com/web/jeb/policies>

MEDICARE CLINICAL LABORATORY FEE SCHEDULES:

Medicare reimburses laboratory services based on its published fee schedules. Co-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule. The Medicare Clinical Laboratory fee schedule may be viewed and downloaded at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files.html>

VALID LABORATORY ORDERS:

Laboratory testing must be ordered by a licensed physician or other individuals authorized by law. If your license has been revoked or suspended, you may no longer order or refer for laboratory testing. Providers must be enrolled in Medicare and Medicaid programs and of a provider type that is eligible to order testing for Medicare and Medicaid patients.

Effective January 6, 2014, CMS instructed the Medicare Administrative Contractors to turn on edits to deny claims for services ordered by providers who have not enrolled their National Provider Identifier (NPI) in the CMS internet-based Provider Enrollment Chain and Ownership System (PECOS). PECOS does require periodic re-enrollment. Please be aware of your status and complete paperwork in a timely manner to avoid being dis-enrolled and losing the ability to order services for Medicare beneficiaries.

TEST ORDERING:

A standard Prometheus requisition form should always be used when ordering tests. If Prometheus receives a test order on a non-Prometheus form or an incomplete Prometheus requisition form, processing of your test order may be delayed. As necessary, Prometheus will contact healthcare providers to have them resubmit the test order on a Prometheus test requisition form or otherwise clarify an unclear test order.

VERBAL TEST ORDERS:

Medicare requires that all orders for laboratory tests be in writing. If a physician or his/her authorized representative orders a test by telephone or wishes to add a test to an existing order, a written order is required to support the verbal order. Prometheus will not perform testing until the written confirmation, or an updated requisition is returned to the laboratory.

PATIENT PRIVACY (HIPAA):

Under the Health Insurance Portability and Accountability Act (HIPAA), Prometheus is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy

and security standards. Our Notice of Privacy Practices can be found on our website at:

<https://www.prometheuslabs.com/notice-of-privacy-practices/>

STARK LAW COMPLIANCE:

Prometheus's policy is to comply with all laws and regulations governing physician self-referral, known as the federal Stark Law. The Stark law's self-referral ban states that if a financial relationship exists between a physician (or immediate family member) and a laboratory and the relationship does qualify under one of the law's exception's, then a physician may not refer Medicare patients to the laboratory and the laboratory may not bill Medicare for services referred by the physician.

FINANCIAL ASSISTANCE PROGRAM:

At Prometheus we are committed to improving lives with innovative diagnostic tests. We understand that providing this testing may not be completely covered by a patient's insurance company or may be burdensome for patients who do not yet have insurance coverage. Prometheus has developed a financial assistance program that allows patients with special financial needs to be eligible for support to assist with some of our testing costs. We encourage those patients who may not be able to pay fully for Prometheus testing to contact us for an assessment of eligibility for financial support in accordance with published federal guidelines.

If you have any questions concerning our Annual Notice or appropriate test use and ordering, please contact our Client Services department at (888) 423-5227 Option 1. For questions about our Financial Assistance Program or Medicare, please contact our Payor Relations Department at (888) 892-8391.