

### **Medicare Annual Notice to Physicians 2026**

Pacific Diagnostic Laboratories (PDL) has implemented a Laboratory Compliance Program based upon the Office of Inspector General (OIG) Compliance Program Guidance for Clinical Laboratories (63 Fed Reg 45076 (Aug. 24, 1998)) “OIG Guidance”). Our compliance efforts are designed to establish a culture within PDL that promotes compliance with the OIG Guidance, Federal and State Laws, and governmental and private health care program requirements. This Annual Notice is based upon the OIG Guidance.

#### **Medical Necessity**

As set forth in the OIG Guidance:

- Medicare will only pay for tests that meet the Medicare coverage criteria and are reasonable and necessary to treat or diagnose an individual patient.
- Tests submitted for Medicare reimbursement must meet Medicare requirements or the claim may be denied.
- Physicians or other authorized individuals must submit diagnosis information (ICD-10 codes) for all tests ordered, as documentation of the medical necessity of the service.
- Medicare generally does not cover routine screening tests.
- Organ or disease related panels will only be paid by Medicare and will only be billed to Medicare when all components are medically necessary.
- Use of client custom panels may result in the ordering of tests which are not covered, reasonable or necessary and those tests will not be paid by Medicare.
- Medicare National Coverage Determinations and Local Coverage Determinations are available through the Centers for Medicare and Medicaid Services (CMS) or the designated Medicare administrative Contractor, Noridian; and can be viewed at: <https://www.cms.gov/medicare-coverage-database/>
- Medicaid reimbursement will be equal to or less than the amount of Medicare reimbursement.

#### **Advanced Beneficiary Notice (ABN)**

Medicare may consider certain tests, diagnoses and frequency combinations not to be medically necessary and will not reimburse them. ABNs should be given to patients by the physician who treats the patient when there is a likelihood that an ordered service will not be paid. Before the service is furnished, the ABN notifies the beneficiary of the likelihood the specific service will be denied and offers the beneficiary the choice either (1) to sign the ABN and agree to pay for the test if Medicare does not, or (2) to not sign the ABN and to not receive the test.

#### **Valid Laboratory Orders**

If a patient presents to a PDL draw station (or if PDL receives a specimen) without a valid test order, or with an order that is ambiguous, vague or unintelligible, PDL will verify which tests the physician wants, prior to performing them and submitting a claim for reimbursement to Medicare.

PDL offers and performs reflex testing for Medicare beneficiaries only when the reflex test is medically necessary. Likewise, PDL offers and performs confirmatory testing for Medicare beneficiaries only when medical necessary. Conditions under which reflex testing or confirmatory testing will be performed for Medicare beneficiaries are communicated on the PDL website. Additional charges may apply for the reflexed test.

Standing orders are only accepted in connection with an extended course of treatment for an individual Medicare beneficiary.

#### **Information**

PDL strives to provide information to patients, physicians (and other individuals authorized to order tests) to enable them to fully understand the services that will be provided by PDL when tests are ordered.

**Medical Director (Clinical Consultant)** can be reached at (805) 569-7367.