



2022 Annual Notice to Providers

Neelyx Labs, Inc. is providing this notice in accordance with the recommendation made by the Office of Inspector General (OIG) of the Department of Health and Human Services. The OIG recommends in its Compliance Program Guidance that clinical laboratories send notices to physicians and other providers who use their services 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 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. Criteria to establish medical necessity for drug testing must be based on patient-specific elements identified during the clinical assessment and documented by the clinician in the patient's medical record. Tests used for routine screening of patients without regard to their individual need are not usually covered by the Medicare Program, and therefore are not reimbursed. As a participating provider in the Medicare Program, Neelyx Labs has a responsibility to make a good faith effort to ensure all tests requested are performed and billed in a manner consistent with all federal and state law regulations. As the physician, you are responsible for documenting medical necessity in the patient's permanent medical record and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to Neelyx Labs (note: The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.)

Medicare National and Local Coverage Determinations

The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare with reference to specific ICD-10 codes. For a complete list of NCD/LCD policies, with test name(s), CPT and ICD-10 code(s), please review:

NCD: <http://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx?bc=AAAAAAAAAAAA>

LCD: <http://wpsmedicare.com/j5macpartb/policy/active/local/>

Test Ordering

A standard Neelyx Labs test requisition form should be used when ordering tests. This requisition is designed to emphasize physician choice and encourage physicians to order only those tests which the physician believes are appropriate and medically necessary for the diagnosis or treatment of each patient. To avoid false claim submission, be sure to: (i) order only those tests necessary for diagnosis or treatment; (ii) provide a diagnosis, sign or symptom for the test(s) ordered; (iii) document this information in the patient's medical record; and (iv) obtain an Advanced Beneficiary Notice (ABN) from the Medicare patient when tests do not meet medical necessity criteria. A completed requisition form should include the following information: collection date, patient name, patient's date of birth, test(s) to be performed, indications as to why the test is being ordered (such as a diagnosis code), and any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results. If Neelyx Labs receives a test order on a non-Neelyx Labs requisition form or an incomplete Neelyx Labs requisition form, processing of your test order may be delayed. As necessary, Neelyx Labs will contact physicians to have them resubmit the test order on a Neelyx Labs test requisition form or otherwise clarify each specific test being ordered. The information you provide on the test requisition should accurately reflect the medical reasons for requesting the specified tests. In the event of a Medicare or compliance audit or request for medical necessity documentation,



Neelyx Labs may request a copy of your medical record documentation to support the medical necessity of the test that was ordered.

Verbal Test Orders

Medicare regulations require 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. In these cases, Neelyx Labs will send a confirmation of the verbal order request to the ordering physician, requesting it to be signed and sent back to the laboratory for its records.

Eligible Provider Enrollment (PECOS)

Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record with a valid National Provider Identifier (NPI) and must be of a specialty that is eligible to order and refer.

<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1305.pdf>

Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), Neelyx Labs 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.

Inducements

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce the referral of tests that are covered by Medicare, Medicaid or other federal health care programs. Any form of kickback, payment or other remuneration that is intended to secure the referral of federal health care program testing business is strictly prohibited and should be reported to Neelyx Labs by calling 630-214-3800.

Medicare Rates

Based upon the OIG's recommendation, we are providing you with a link to the Medicare laboratory fee schedule, which may be found on the CMS webpage at <http://www.cms.hhs.gov/ClinicalLabFeeSched>. You should note that the Medicaid reimbursement amount may be equal or less than the amount of Medicare reimbursement that Neelyx Labs will receive on the tests you order.

If you have any questions concerning this notice or appropriate test use and ordering, please contact us at legal@neelyx.com or (630) 214-3800.