

Legacy Laboratory Services

ANNUAL NOTICE OF LABORATORY COMPLIANCE FOR PHYSICIAN AND NON-PHYSICIAN PROVIDERS 2019

Legacy Laboratory Services is providing this annual notice in accordance with recommendations made by the Office of Inspector General (OIG) and the US Department of Justice, to provide physicians with education about specific aspects of our Laboratory Compliance Program and the important responsibilities we share.

This notice will highlight areas of regulatory focus and oversight. It is intended to help our healthcare partners complying with administrative protocols necessary to mitigate any related risks to either party.

Please review this compilation of applicable Medicare regulations, billing rules, compliance guidelines and related laboratory policies & procedures. If you have questions about any content in this notice, we encourage you to contact us for more information.

ARE YOU ABLE TO ORDER LABS FOR MEDICARE PATIENTS?

All ordering providers are required to have a valid National Provider Identifier (NPI#), available via <https://nppes.cms.hhs.gov/NPPES/Welcome.do>

As of 2014, Medicare requires individuals referring orders for laboratory services be registered in the CMS Provider Enrollment, Chain and Ownership System (PECOS). Eligible providers have the option of either enrolling, or officially 'opting-out' – and **MUST do one or the other**. Additional information on PECOS and how to enroll, or how to OPT-OUT, may be viewed at:

https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MEDEnroll_PECOS_PhysNonPhys_FactSheet_ICN903764.pdf

IMPORTANT EXCEPTION: Naturopathic Physicians (ND's), Chiropractic Physicians (DC's), and Pharmacists (Rph/MTM) are NOT permitted to enroll in, or opt-out of Medicare, and thus cannot order/refer any lab testing for any patient with Original Medicare & certain Medicare Advantage plans.

Legacy Laboratory may only bill Medicare & certain Medicare Advantage plans for testing ordered by licensed, enrolled physicians or non-physician practitioners authorized by law to order laboratory testing.



ARE YOU SUBMITTING A VALID LABORATORY ORDER/REQUISITION?

To ensure accurate processing and patient identification, efficient patient registration, and timely reporting of lab results, all valid lab orders must include the ordering practitioner's name & credential, practice address and NPI number, the patient's full legal name, date of birth, gender, date and time of collection (if applicable), and source (if applicable). Hand-written orders (i.e.: scripts) must be legibly signed and dated by the provider. The ordering provider's name must be printed below any signature that is not legible. Signature stamps are NOT acceptable.

One-time orders are only valid for 90 days from the original order date.

Recurring orders are acceptable only in connection with extended treatment by the same ordering physician, and with the same diagnosis code(s). Recurring orders **must** include both the frequency and duration for the order, not to exceed 365 days from original order date. 'PRN' orders are not acceptable.

Due to the ever-increasing complexities of insurance coverage, and to ensure proper billing, please attach a front/back copy of the patient's insurance card(s) to the lab orders. If incomplete insurance information is submitted, the patient may receive an itemized statement requesting payment.

The pre-printed lab 'requisition' is the tool used to communicate the physician order to the lab, but it is NOT considered the valid 'order' as defined by Medicare. Upon request by Legacy Laboratory or its payers/auditors, ordering providers are required to provide any/all chart documentation (including physician signature) that reflects and supports the authenticity, intent-to-order, and medical necessity of any/all lab tests indicated on the requisition(s) submitted.

ARE YOU CODING CORRECTLY? PROVIDING ACCURATE ICD-10 CODING AND DIAGNOSIS INFORMATION?

Section 4317 of the Balanced Budget Act of 1997 **requires** ordering/referring providers to submit accurate & complete diagnosis information on any/all lab orders. The information submitted must reflect medical necessity and best describe the primary reason each lab test is being ordered.

You may submit this information in either of the following formats – alpha/numeric ICD-10 code(s) to the highest level of specificity, or narrative description(s) of diagnosis, signs/symptoms, reason for testing, or indication. Any information submitted must also be legibly documented (by test) in the patient's medical record, and must be signed by the ordering provider.

If testing is requested in the absence of any signs/symptoms, the most appropriate screening code (see 'Z' codes in your coding reference) must be submitted for each test as applicable to the test ordered.

Coding cannot be assigned based on a "rule-out" (r/o) narrative description, must not reflect information available only after the lab testing is complete, and must NOT be assigned for reimbursement-purposes only.

Only the ordering physician knows why each lab test is being ordered. The Laboratory cannot assign diagnosis information to any patient or test, but we are permitted to translate a physician-assigned narrative description into the appropriate ICD-10 code(s) if/when possible.

ICD-10 codes are updated annually and new/updated/more-specific codes become effective October 1st of each year. Please review them annually to ensure accurate code submission to the highest level of specificity required. ICD-9 codes have not been valid since 2015.

ARE YOU COMMUNICATING MEDICAL NECESSITY?

As a health care provider, you may order any test(s), including screening tests, which you believe are appropriate for the treatment of your patient. However, Medicare will only pay for tests that are considered medically-necessary for the diagnosis or treatment of the individual patient. Insurance claims submitted for laboratory services will only be paid by Medicare and other insurance payors if the service is “covered, reasonable, and necessary” as defined by payor-specific criteria, which is based on the primary (1st) ICD-10 code supplied for each test ordered.

The medical necessity of each test must be specifically documented in the patient’s permanent medical record/chart, must reflect any/all ICD10 codes or narrative descriptions submitted on the lab requisition, and must be signed by the ordering physician.

Remember that providing evidence of medical necessity for each test ordered is a requirement for your participation with Medicare, Medicaid and other insurance plans.

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.

WHAT’S THE DIFFERENCE BETWEEN DIAGNOSTIC, SCREENING, PREVENTIVE, OR ROUTINE?

Statutorily, Medicare *does NOT* cover any lab testing for routine and/or screening purposes. However, Medicare *does* cover some Preventive lab tests (PSA, Glucose, Lipids, etc.) if ordered as required by Medicare. For Preventive benefit information including test names, specific CPT codes, required ICD-10 code(s) and frequency limitations, please reference:

<https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html>

Many preventive lab services are available for payment if ordered as required by the patient’s insurance plan. Those tests available for coverage must be coded with specific, sometimes single ‘Z’ code(s) as defined by the payor. Any test coded as ‘diagnostic’ rather than ‘screening’ (based on the ICD-10 code submitted) will not be payable at 100% per their Preventive benefit.

Be cautious if a patient comes to you requesting certain lab testing and you determine the testing is NOT medically-necessary. This type of lab order cannot be billed to any patient insurance; it must be billed directly to the patient. If you decide to comply with their request, document the request in the medical record and inform the patient they will be financially responsible for all charges. Please provide a separate order for this type of testing and indicate “PATIENT REQUESTED” on the requisition. Do not submit diagnosis coding for this type of testing.

WHAT ARE MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS?

CMS has developed National Coverage Determination (NCD) Policies that restrict Medicare coverage for certain lab tests/CPT codes. In addition, Noridian Administrative Services, LLC (02402, MAC-Part B)

continues to develop Local Coverage Determination (LCD) Policies that restrict Medicare coverage for additional testing. Any lab test contained in one of these NCD/LCD policies must be screened for medical necessity based on the applicable policy and the primary diagnosis code assigned.

For a complete list of NCD/LCD policies, with test name(s), CPT's and covered ICD-9 code(s), please review:

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

LCD = <https://www.noridianmedicare.com/partb/coverage/active.html>

If a 'non-covered' diagnosis is used, the patient must be notified of their potential financial liability prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice (ABN). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. The completed, signed original ABN must be attached to the original lab order prior to specimen submission. Per Medicare rules, requesting the ABN on all Medicare beneficiaries is an unacceptable practice and is not permitted.

For an ABN tutorial: <https://med.noridianmedicare.com/web/jfb/topics/abn/abn-tutorial>

Copies of the customized Legacy Lab Advance Beneficiary Notice (ABN) and the ABN Price List (needed to complete the required cost estimate portion of the ABN) may be ordered along with other supplies.

Note that Medicare Advantage Plans do not accept Medicare ABN's. If you order testing that may not be covered due to medical necessity review, you'll need to follow the payor's "Pre-Determination Process" prior to specimen collection.

ARE YOU GETTING THE REQUIRED PRE-AUTHORIZATION FOR LAB ORDERS?

Insurance payors continue to increase oversight and restrict access by requiring pre-authorization for certain lab tests, including but certainly not limited to any Genetic markers, Cytogenetics testing, Drug testing, Allergy & Celiac testing, etc. Please work with your patient to review their payor-specific preauthorization requirements. Any preauthorization paperwork must be completed by the ordering provider's office prior to submission of any lab orders and/or specimens. Please include the 'preauth' number on the lab order, along with any related documentation. If preauthorization is required by the payor but is not done by the ordering provider prior to submission, the laboratory may delay or suspend testing until the required authorization can be completed. If not authorized, the laboratory is unable to bill charges to the patient.

ARE YOU ORDERING ORGAN/DISEASE PANELS/LAB-CUSTOMIZED PANELS?

Before ordering, carefully review the components of any laboratory test panel, whether AMA-assigned, laboratory-developed, or client-developed. Only order any panel when ALL the individual components of the panel are medically-necessary as determined by specific ICD-10 code(s) and documented in the patient's medical record/chart. If any panel component is not medically-necessary, do not order the panel; order only those individual tests that are medically-necessary.

ARE YOU ORDERING REFLEX TESTING?

Some lab tests may trigger additional testing and additional charges based on laboratory policies that reflect standard of care, or by request from the ordering physician. All procedures that contain a reflexive

pathway are identified in our test directory, including criteria that will lead to additional charges and the specific CPT code(s) that will be billed. Test names should include 'w/reflex' to clearly identify them.

OTHER VALUABLE INFORMATION ABOUT THE LEGACY LABORATORY COMPLIANCE PROGRAM INCLUDES:

1. Medicaid reimbursement will be equal to or less than the Medicare reimbursement amount. Medicare's Clinical Laboratory Fee Schedule (CLFS), including all CPT codes, can be found at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html>
2. Because we are a CMS-contracted provider, we are prohibited from billing any federal program for testing requested by any provider excluded from participation. If your license has been revoked or suspended, please notify the laboratory immediately. Lab testing ordered by any sanctioned provider should not be submitted to Legacy Lab, and will not be accepted.
3. The OIG/Department of Justice takes the position that an individual who knowingly causes a false claim to be submitted may be subject to sanctions or remedies available under civil, criminal and administrative law. The laboratory will not knowingly bill Medicare for testing that is non-covered, unreasonable and/or unnecessary.
4. **If the laboratory receives an order without any diagnosis information, or is unable to bill for testing performed because the coding supplied doesn't meet medical-necessity requirements, we will attempt to contact the ordering provider to gather additional coding information that may have been documented in the patient's chart but wasn't noted on the original lab requisition. It is illegal to code solely for reimbursement purposes. The laboratory may not assign diagnosis information.**
5. Supplies required for the collection of specimens sent to our laboratory will be provided upon request. Due to Stark II/Anti-Kickback statutes, supply volumes must reasonably match volumes of testing received.

As you can see, Legacy Laboratory Services has an active Compliance Program that reflects our commitment to conduct business in compliance with all federal, state and local laws, and to adhere to all program requirements for federal, state and contracted private health plans.

Your partnership with Legacy Laboratory Services is fundamental to the success of our compliance program, and we thank you for your attention, cooperation and continued participation.

Again, if you have any questions about information contained in this notice, or other issues/concerns related to laboratory financial compliance, or lab coding, please contact:

Sharon DeCicco, MBA, MT (ASCP), Director of Laboratory Business Operations @ sdecicco@LHS.org or 503-413-5083

Mike Castoldi, Financial Compliance Analyst/Lab Coding Specialist @ mcastold@LHS.org or 503-413-5228

For questions or issues related to clinical or regulatory compliance, please contact:

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