ANNUAL NOTICE OF LABORATORY COMPLIANCE FOR
PHYSICIAN AND NON-PHYSICIAN PROVIDERS
2020

Legacy Laboratory Services provides this annual notice in accordance with recommendations made by the Office of Inspector General (OIG) and the US Department of Justice, to educate physicians and non-physician providers about specific aspects of our Laboratory Compliance Program and the important responsibilities we share.

This notice will highlight areas of regulatory focus and administrative oversight. It is intended to help our healthcare partners understand and comply with the many rules that attempt to mitigate the compliance risk to either party. Please review this compilation of important Medicare regulations, billing rules, and other related compliance guidelines.

If you have questions about any content in this notice, we encourage you to contact us for more information.

ARE YOU PERMITTED TO ORDER LABS FOR MEDICARE PATIENTS?

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

In addition, Medicare requires any eligible provider be registered in the CMS Provider Enrollment, Chain and Ownership System (PECOS). All eligible providers are required to enroll or officially ‘opt-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/EnrollmentResources/provider-resources/Med-Prov-Enroll-MLN9658742.html

Naturopathic Physicians (ND’s), Chiropractic Physicians (DC’s), and Pharmacists (RPh/PharmD) CANNOT enroll or opt-out of Medicare and are not permitted to order or refer any diagnostic testing for patients with Original Medicare & certain Medicare Advantage plans.

Testing not ordered by licensed, enrolled physicians or other qualified nonphysician practitioners acting within the scope of their practice, and in compliance with Medicare requirements will be denied as not reasonable and necessary.
ARE YOU SUBMITTING A VALID LABORATORY ORDER/REQUISITION?

Although the pre-printed ‘requisition’ is the tool used to communicate the physician order to the lab, it is NOT considered the valid ‘order’ as defined by Medicare. Each valid order must be accurately documented in the patient’s medical record and signed by the ordering provider.

To ensure accurate patient identification, timely reporting of lab results, and compliance with state law, all valid lab requisitions must include the ordering practitioner’s name with credential, practice address and NPI number, the patient’s full legal name, date of birth, gender, date and time of collection, and specimen source (where applicable). Any hand-written requisitions (i.e. ‘script’) must be legibly signed and dated by the ordering provider. The provider’s name must be printed below any signature that is not legible. Signature stamps are NOT acceptable.

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

Recurring laboratory orders are acceptable only in connection with extended treatment by the same ordering physician with the same diagnosis code(s). Recurring orders must include specific frequency and duration; not to exceed 365 days from original order date. ‘PRN’ orders are not acceptable.

Upon request by Legacy Laboratory or its payors/auditors, ordering providers are required to provide all pertinent medical records, including physician signature, that reflect and support the intent-to-order and medical necessity of any/all lab tests indicated on the requisition(s) submitted.

Also, due to the ever-increasing complexities around insurance coverage and to ensure proper billing, it is best practice to attach a front/back copy of the patient’s insurance card(s) to each lab requisition. If incomplete insurance information is submitted, the patient may receive an itemized statement requesting direct payment.

ARE YOU CODING YOUR LAB ORDERS CORRECTLY?

The laboratory is dependent on the diagnosis or clinical history information submitted on the request for testing. Since the majority of clinical lab tests are not interpreted by a pathologist, the information received on the requisition will reflect the diagnosis submitted on the claim for reimbursement and will – or will not – support medical necessity and payment for testing. The laboratory cannot assign coding.

All lab tests must be submitted with a valid diagnosis code to the highest level of specificity or comparable narrative.

Codes that describe signs and symptoms, as opposed to diagnoses, should be reported when a diagnosis has not yet been established.

Do not code diagnoses documented as “rule out”, “suspected”, or other similar terms indicating uncertainty. Rather, code the condition to the highest degree of certainty for that visit, such as signs, symptoms, previous abnormal test results, or other reason for visit.

When a non-specific diagnosis code is submitted, the underlying sign, symptom or condition described by that code must be related to the indications for the test.
Coding rules for outpatients stipulate that the encounter be coded only to the level that is definitive at the time of order and should not reflect information available only after the lab testing is complete.

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 MUST NOT be assigned specifically to garner reimbursement or increase the patient’s benefit level.

ICD-10 codes are reviewed and updated annually, with new/updated/more-specific codes becoming effective October 1st of each year. Please research them annually to ensure accurate code submission to the highest level of specificity required. ICD-9 codes have not been valid since 2015 and should not be submitted.

**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, 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 largely based on the single primary ICD-10 code assigned to each test ordered.

The medical necessity of each test must be specifically documented in the patient’s permanent medical record/chart, must reflect any ICD10 codes or narratives 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?**

Screening/Preventive tests are for people believed to be healthy and performed in the absence of signs, symptoms, complaints or personal history of disease or injury.

Diagnostic tests are for people believed to have a problem and to establish the presence (or absence) of disease as a basis for treatment decisions in symptomatic or screen positive individuals.

Individual tests cannot be coded with both diagnostic and routine/screening codes. Once a patient has been diagnosed with a relevant condition, screening codes are no longer appropriate.

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:
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 payor policy. 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 THE MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS?

CMS has developed National Coverage Determination (NCD) Policies that restrict Medicare coverage for certain lab tests on a national basis. In addition, Noridian Administrative Services, LLC (02402, MAC-Part B) continues to develop Local Coverage Determination (LCD) Policies that restrict Medicare coverage for an additional list of tests. Any CPT contained in one of these NCD or LCD policies must be screened for medical necessity based on the applicable policy and the primary diagnosis code assigned.

For a complete listing of NCD/LCD policies, with test name(s), CPT’s and listing of ICD-10 code(s) considered medically necessary, please review:


If a ‘non-covered’ diagnosis is used when ordering any lab test covered by NCD/LCD policy, 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. Completing an ABN for every Medicare beneficiary 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. Please contact the payor for detailed information.

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 genetic markers, cytogenetic testing, drug testing, allergy & celiac testing, etc. Please work with your patients to review their payor-specific preauthorization requirements. Any preauthorization paperwork must be completed by the ordering provider’s office prior to the submission of any lab orders or specimens. Please include the ‘preauth’ number on the lab requisition,
along with any related documentation. If preauthorization is required by the payor but is not completed prior to test submission, the laboratory may delay or suspend testing until the required authorization is completed. If not authorized, the laboratory is not permitted to bill charges to the patient.

ARE YOU ORDERING ORGAN/DISEASE PANELS OR LAB/CLIENT 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 if each/every individual component of the panel is 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.

ARE YOU ORDERING REFLEX TESTING?

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that additional, related testing is medically appropriate based on standard of care or by request from the ordering physician.

All procedures that contain a reflexive pathway are identified in our test directory and include criteria that will lead to additional charges and the specific CPT code(s) that will be billed. Our test directory can be found at: https://www.legacyhealth.org/for-health-professionals/refer-a-patient/laboratory-services.aspx

Test names should include ‘w/reflex’ to clearly identify them for ordering providers.

ADDITIONAL INFORMATION ABOUT THE LABORATORY COMPLIANCE PROGRAM

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 the required 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 any additional coding information documented in the patient’s chart but inadvertently not submitted on the original lab requisition. Again, it is illegal to code solely for reimbursement purposes.

5. Supplies required for the collection of specimens sent to our laboratory will be provided upon request. Due to Stark Law/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.

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:

    Susan Harris, MT (ASCP), Clinical/Regulatory Compliance Consultant @ sharris@LHS.org or 503-413-5028