Annual Notice of Laboratory Compliance
December 2020

Dear Provider/Client:

This annual notice is in compliance with the guidance of the Office of the Inspector General (OIG) and the regulations and requirements of the Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS.), available at: https://oig.hhs.gov/authorities/docs/cpglab.pdf The Office of the Inspector General (OIG) recommends laboratories provide notices to physicians and other ordering providers annually as part of their compliance plan. Trident Labs is issuing this notice in accordance with this recommendation. This letter serves as our annual notice and provides helpful information regarding the ordering and processing of clinical laboratory tests.

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.

Licensed Physicians and Non-Physician Practitioners (NPP):
A clinical laboratory may only bill Medicare (including some Medicare Advantage plans) and Medicaid for testing ordered by a licensed, enrolled physician or non-physician practitioners authorized by law to order laboratory tests. 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 must 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. Naturopathic Physicians (ND's) and Chiropractic Physicians (DC's) are NOT permitted to opt-out or enroll in Medicare, and thus cannot order/refer any lab testing for any patient with Original Medicare & certain Medicare Advantage plans.

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 If your license has been revoked or suspended, please notify the laboratory immediately.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 Trident Labs, and will not be accepted.

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. The medical need 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 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 or other insurance payors if the service is "covered, reasonable, and medically necessary" as defined by payor-specific criteria, and based on the primary 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 coding or narrative submitted on the lab requisition, and must be signed by the ordering physician. As a Medicare participating provider, Trident Labs has a responsibility to make good faith efforts to ensure that all tests requested are performed and billed in a manner consistent with all federal and state laws and regulations.

The OIG takes the position that physicians or other individuals authorized by law to order 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.

Diagnosis Information:

Section 4317 of the Balanced Budget Act of 1997 requires all ordering/referring providers to submit diagnosis information on the laboratory order for submission of a Medicare claim. The information must indicate medical necessity and best describe the primary reason each lab test is being ordered. The diagnosis information supplied should accurately describe the patient's condition on the date of service as documented in the patient's medical record. This information may be submitted 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/chart, and signed by the ordering provider.

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.

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.

Trident Labs will contact the providers/clients via telephone call or fax for all requisitions that do not include this required information.

MEDICARE NATIONAL AND LOCAL COVERAGE DETERMINATIONS:

Not all laboratory services are covered by Medicare. The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain lab tests. These policies identify the conditions for which the included tests are or are not covered or reimbursed by Medicare, typically by reference to specific ICD-10 codes that are deemed to support coverage. LCD policies can be accessed on the Medicare website. 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 the most current information regarding Medicare coverage, please use this link: www.cms.gov/medicare-coverage-database.

If a 'non-covered' diagnosis is used, the patient must be notified of their financial liability prior to specimen collection and given the opportunity to sign the Advance Beneficiary Notice of Noncoverage (ABN). The ABN must be completed for any Medicare patient where claim denial is suspected based on medical necessity or frequency limitations. It is used to document that the patient has been made aware that Medicare may not pay for services and has agreed to pay the laboratory in the event payment is denied by Medicare. A separate ABN must be used for each encounter. The signed, original ABN must be attached to the requisition when the specimen(s) are submitted to the laboratory. Per Medicare rules, requesting the ABN on all Medicare beneficiaries is considered an unacceptable practice.

The most current ABN is must be used and may be downloaded from the CMS website: https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN

Urine Drug Testing

On October 01, 2015, and updated on May 10, 2020, our Medicare Administrative Contractor Wisconsin Physician Services Insurance Corporation (WPS), implemented an LCD entitled **"Drug Testing (L34645)".** This policy, among other things, provides guidance regarding covered indications, limitations, and/or medical necessity. Article A56915 Billing and Coding: Drug Testing contains billing, coding, or other guidelines that complement the Local Coverage

Determination (LCD) for Drug Testing L34645. These documents can be accessed on the Medicare website at https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?CoverageSelection

Reflex Testing

Reflex testing occurs when initial test results are positive or outside normal parameters and indicate that a second related test is medically appropriate based on laboratory policies that reflect standard of care, or by request from the ordering physician which may trigger additional charges. Please see the laboratory test directory for a list of tests that may require reflex testing. If you DO NOT want reflex testing for any of the tests indicated in the directory, please clearly communicate this on the laboratory requisition. Please contact the laboratory if you have any questions about reflex tests.

Submit Valid Laboratory Orders/Requisitions:

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

One-time orders are 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 complexity of insurance billing, please attach a front/back copy of the patient's insurance card(s) to ensure proper billing. 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 Trident Labs 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.

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 Drug testing. 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 preauthorization 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 processing until the required authorization can be completed. If not authorized, the laboratory is unable to bill charges to the patient.

Prohibited Referrals and Inducements

It is the policy of Trident Labs to comply with both the Physician Self-Referral Law (Stark) and the Anti-Kickback Statute. Stark Law states that if a financial relationship exists between a physician (or their immediate family member) and a laboratory, the physician may not refer Medicare beneficiaries to the laboratory, and the laboratory may not bill Medicare for any services referred by the physician unless the financial relationship between the parties falls into one of the law's exceptions. The Anti-Kickback Statute prohibits the knowing or willful offer, payment, solicitation, or receipt of remuneration

Lastly, the Model Compliance Plan also suggests that we provide you with a copy of the Medicare Laboratory fee schedule and advise you that the Medicaid reimbursement amount may be equal to or less than the amount of Medicare reimbursement that the hospital will receive on the tests you order. The Medicare fee schedule may be found on the CMS webpage at http://www.cms.gov/center/clinical.asp under the heading "Billing/Payment".

Trident Labs is committed to conducting business in accordance with all federal, state and local laws, and to adhere to all program requirements for federal, state and private health plans.

Please take a few minutes to review this information with your appropriate staff. We value your business and appreciate the opportunity to serve your laboratory needs in conjunction with these initiatives. If there are further questions regarding this information, please contact your account representative or Trident Labs at 855.875.2532.

Thank you.