In accordance with Premier Biotech Labs, LLC's (Premier Biotech) compliance policies and the Office of Inspector General's (OIG) recommendation, Premier Biotech sends this annual notice to physicians and other providers who use our services, at least once a year, to inform recipients of the laboratory's policies for test ordering and billing and to provide certain other information regarding the laws and regulations that govern laboratory services. The following information is intended to promote awareness of and provide education regarding some of the applicable federal regulations and to explain that physicians are required to furnish appropriate documentation when ordering testing services. This notice is not, however, a comprehensive guide to federal and/or state laws governing the ordering of our services. If you have questions about the contents of this notice, we encourage you to contact us or a competent healthcare advisor for more information.

Medical Necessity

Medicare and state Medicaid programs will only pay for tests that meet their respective 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 needs are not usually covered by Medicare or Medicaid, and therefore are not reimbursed. As a participating provider in the Medicare program and as a Medicaid provider in many states. Premier Biotech has a responsibility to educate physicians and to implement test ordering procedures to help ensure all tests requested are performed and

billed in a manner consistent with all federal and state law regulations. As the physician or referring clinician, you are responsible for ordering tests only when they are medically necessary, 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 to Premier Biotech. The medical necessity of each test ordered must be documented in the patient's medical record and must be sufficient to support all coding submitted with the lab requisition.

The OIG takes the position that a clinician 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 and Medicaid payments to laboratories are based in part on each patient's principal and secondary diagnoses, as attested by the ordering clinician by virtue of his or her signature on the test request. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

Medicare National and Local Coverage Determinations

Medicare publishes National Coverage Determinations (NCDs) and individual Medicare Administrative Contractors (MACs) 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, typically by reference to specific ICD-10 codes that are deemed to support coverage, and include frequency limitations and other conditions of coverage.

As of December 1, 2015 (and effective as of the time of issuance of this notice), our MAC, National Government Services, Inc. (NGS) implemented an LCD entitled "Urine Drug Testing (L36037)." This policy (attached as Exhibit A), among other things, provides guidance regarding covered indications, ICD-10 codes that support medical necessity and expected frequency for Urine Drug Testing (UDT). For the most current information regarding Medicare coverage, please use this link: https://www.cms.gov/medicare-coverage-database/.

Minnesota Medicaid Policy

The Minnesota Department of Human Services publishes its own coverage guidance in its Provider Manual. Included in that is a Laboratory and Pathology Services section that discusses covered services and includes a section entitled "Drug Testing." This section identifies the conditions of coverage, including frequency limitations and documentation requirements. A copy of the Laboratory and Pathology Services section can be found at: https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_144353

Test Ordering

A standard Premier Biotech test requisition form (whether via our web-based platform or in paper form) is required when ordering tests. Premier Biotech's requisition form is designed to encourage clinicians to only order tests which the clinician believes are appropriate and medically necessary for the diagnosis or treatment of each patient. If Premier Biotech receives a test order on a non-Premier Biotech requisition form or an incomplete requisition form, the processing may be delayed. As necessary, Premier Biotech will

contact clinicians to have the test order resubmitted on a Premier Biotech Lab form, to clarify the test(s) being ordered or to complete the requisition form. By signing the test requisition, a clinician is attesting to the fact that the submitted test request is reasonable and necessary and they have received no inducement to order any test from Premier Biotech. 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, and source (when applicable).

The ordering clinician must ensure that his/her updated information is timely provided to Premier Biotech if there are any changes (i.e., address, 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. Upon request by Premier Biotech or its payors/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.

Verbal Test Orders

Medicare regulations require that all orders for laboratory tests be in writing. If a provider 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, Premier Biotech will require the ordering clinician to send a written confirmation of the verbal order request for its records.

Diagnosis Information

Section 4317 of the Balanced Budget Act of 1997 requires the physician or authorized ordering party to submit diagnosis information on the laboratory order for submission of a Medicare claim. The diagnosis information supplied should accurately describe the patient's condition on the date of service as documented in the patient's medical record. Providers will be contacted by Premier Biotech for all requisitions that do not include this required information.

Standard or Custom Profiles

Premier Biotech recognizes that some providers have their own profiles they prefer to utilize for their patients. If all components of the profile are not medically necessary, you should only order the medically necessary individual tests or a profile that contains only the medically necessary tests. Screening or investigational use only tests are generally not covered by Medicare, with some exceptions for Wellness Screens. As a Medicare participating provider, Premier Biotech 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.

Patient Privacy (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), Premier Biotech is a health care provider and a covered entity. It is our policy to fully comply with 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.

Prohibited Referrals

It is the policy of Premier Biotech to comply with all aspects of the laws and regulations governing physician self-referral, including most notably the federal Stark law. The Stark law's self-referral ban states that if a financial relationship exists between a physician (or an immediate family member) and a laboratory (or certain other kinds of healthcare providers), and the relationship does not fit into one of the law's exceptions, then (a) the physician may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the physician. The kinds of relationships between laboratories and physicians that may be affected by these laws include the lease or rental of space or equipment and the purchase of medical or other services by a laboratory from a referring physician.

Medicare Rates

Premier Biotech's test lists are attached hereto as Composite Exhibit B. Please contact Premier Biotech for rate information.

Billing Practices

Claims for reimbursement are submitted only for tests that have been both ordered and performed. If the laboratory receives a specimen without a completed test order or with an ambiguous order subject to multiple interpretations, the ordering clinician will be contacted to determine what test(s) are to be performed before testing is conducted or a claim for reimbursement submitted. If relevant diagnostic information is not provided at the time the service is ordered, Premier Biotech will contact the ordering clinician to obtain the required information. Providers are required to provide

information for billing and medical necessity when requesting tests and other documentation as necessary.

The ordering clinician should be aware that Premier Biotech may only bill Medicare for testing ordered by a licensed physician or other individuals authorized by law to order clinical laboratory tests. If your license has been revoked or suspended, or your enrollment in a federally funded health plan has been suspended or revoked, please notify Premier Biotech immediately.

Patient Billing Policy

Insured patients are billed Deductibles, Co-Insurance and Co-Payments as required by their Insurance Provider. Premier Biotech reserves the right to use resources available to search for active insurance if information is not provided or if the order is marked "Uninsured" or "Patient Does Not Have Insurance Coverage."

Financial Assistance Programs

Premier Biotech understands that providing quality patient care has a related cost, which in some situations may be burdensome for patients and result in some patients avoiding certain necessary services because they are concerned about the expense. Premier Biotech is committed to delivering the best patient care to all. Patients with special financial needs may be eligible for support or options related to testing costs, and should contact Premier Biotech for more information.

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.

Thank you.

Attachments:

Files can be accessed via the following links.

EXHIBIT A – NGS LCD

https://premierbiotech.com/innovation/wp-content/uploads/2021/03/Exhibit-A-to-2021-Annual-Notice-9336959x7AB84.pdf

COMPOSITE EXHIBIT B – Test lists

https://premierbiotech.com/innovation/wp-content/uploads/2021/03/Exhibit-B-to-2021-Annual-Notice-9336962x7AB84.pdf