Annual Notice of Laboratory Compliance

Dear Providers/Clients,

At Pathology Group of Louisiana (PGL), we are committed to full compliance with all applicable federal and state laws and regulations, third party payer requirements, and industry best practices. The Office of Inspector General (OIG) of the Department of Health and Human Services recommends in its Model Laboratory Compliance Plan that laboratories send an annual notice to physicians advising them of the elements of the laboratory's compliance program (available at http://oig.hhs.gov/authorities/docs/cpglab.pdf). This letter serves as PGL's annual notice and provides helpful information regarding the ordering and processing of laboratory tests.

Medical Necessity

Consistent with coverage requirements issued by the Centers for Medicare and Medicaid Services ("CMS"), we require a completed laboratory test requisition form with each specimen submitted to us for testing that includes a diagnosis (in ICD-10 or narrative description format) from the ordering physician supporting medical necessity before we can perform a laboratory test. CMS also requires a signed physician order be maintained in the patient record for each test ordered or the signature of the ordering physician/pathologist on the test requisition form attesting to the medical necessity of each test, or panel of tests ordered. It is important to note that the OIG takes the position that physicians and other authorized individuals who order medically unnecessary tests or who knowingly causes 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.

In addition to medical necessity requirements, CMS has developed specific National Coverage Determinations ("NCDs") for certain laboratory tests, which can be accessed on the CMS website at https://www.cms.gov/medicare-coveragedatabase/overview-and-quick-search.aspx. Further, CMS' Medicare Access Contractors ("MACs") and fiscal intermediaries have published Local Coverage Determinations ("LCD") for certain laboratory tests that are specific to a patient's geographic location or jurisdiction. Laboratory tests that do not meet applicable NCD or LCD coverage requirements are considered "noncovered tests" and, depending on the circumstances, the patient may be financially responsible. However, in order for the laboratory to bill the patient, Medicare (and other payers) require that a patient sign an Advance Beneficiary Notice ("ABN") informing them of the non-covered status of a test prior to the test being performed. Since we do not interact directly with patients, it is the responsibility of the ordering physician to be familiar with applicable NCD and LCD coverage rules, including ABN requirements, to ensure that informed medical necessity determinations, which take into consideration a patient's financial ability, are made for each patient and are supported by a signed order in the patient's medical record.

Medicare Reimbursement Fee Schedules

Medicare reimburses laboratory testing services through either the Physician Fee Schedule or the Clinical Lab Fee Schedule, depending on the type of test. If you would like a copy of either of these fee schedules, please refer to the Medicare Fee-for Service Payment section of CMS's website at https://www.cms.gov/Medicare/Medicare.html . Medicaid reimbursement is generally equal to or less than the amount of Medicare reimbursement.

Requisition Requirements

Each test requisition form must contain complete patient demographic information including the patient's full legal name, date of birth ("DOB"), gender, and insurance information, if applicable. If there are two insurances (e.g., Medicare and a secondary payer), all insurance information is required for both payers. For all test requisition forms that indicate that we should bill a third party payer, please also include a copy of the patient's insurance card with each

requisition form. Please note that if any required information is missing on a test requisition form, it may impact turnaround time for the test results while we gather the missing information.

Specimen Requirements

Clients are responsible for submitting specimens which are properly labeled and have two patient identifiers in addition to meeting the submission requirements for all testing requested.

Billing Information and Client Billing

Billing Patients

Clients are advised that patients will receive invoices from PGL in certain situations. Although, we are an "in network" or contracted laboratory services provider with a multitude of national and regional third party payers, there are certain plans with which we do not have a contract ("out-of-network"). If we are an out-of-network laboratory with a payer and the payer makes payment directly to a patient for the lab services we perform, we must invoice the patient for such services to obtain payment. In addition, in situations in which we are an in-network provider with a patient's insurance company or government payer such as Medicare, we are contractually obligated to invoice patients for any co-payment, co-insurance or deductible that a payer determines is the patient's responsibility. Some payers for which we are an in-network laboratory may also deny payment for certain tests that we offer, because they have not yet established reimbursement for such services or have otherwise determined that they are "non-covered services". In such situations, we are legally required to make good faith efforts to collect on any amounts due directly from the patients. Although we may offer discounts and/or payment plans to patients in accordance with applicable law, many patients are concerned about the expense of such tests. As stated previously, it is the responsibility of the treating physician to inform each patient of any tests that may not be covered by their insurance and, for Medicare patients, to ask that they sign an ABN which lists the non-covered tests and pricing. This allows each patient to make informed decisions on their care with full knowledge of the financial responsibility they may incur.

Reflex Laboratory Tests

Consistent with best practices and the standards of care in laboratory medicine, pathologists may order additional laboratory tests (reflex tests) on specimens based on their independent judgment and determination of medical necessity for the patient, as well as the results of other adjunct tests performed on a specimen. Please be advised that in the event you order a test from PGL, any of our pathologists may, in their discretion as the interpreting pathologist, order additional tests on a specimen based on their independent medical judgment and if clinically indicated for the patient.

Thank you for your attention in these important matters of mutual concern. For more information about the OIG's compliance requirements, please visit: https://oig.hhs.gov/compliance/physician-education/index.asp . To the extent you have questions, please feel free to contact either of the Compliance Officers, at the numbers below.

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Sincerely,
Pathology Group of Louisiana
Board of Directors