PathGroup
Physician Centered. Patient Focused.

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January 27, 2020

Dear Valued Client,

At PathGroup, we are committed to full compliance with all applicable federal and state laws and regulations, third party payer requirements, and industry best practices. To that end, and consistent with recommendations of the Office of the Inspector General ("OIG") for the U.S. Department of Health and Human Services Compliance Program Guidance for Clinical Laboratories, the purpose of this annual letter is to inform you about certain important laboratory practices and the regulations governing them.

Client Services

To assist with laboratory testing questions, we encourage our physicians or other clinicians authorized to order tests to contact PathGroup Client Services at 888.474.5227 for assistance with any concerns that may arise.

Medical Necessity

Consistent with documentation 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 from the ordering physician supporting medical necessity before we can perform a laboratory test. CMS also requires a signed order be maintained in the patient record for each test ordered or the signature of the ordering provider on the test requisition form or a current standing order attesting to the medical necessity of each test ordered. As the physician, 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. We fully cooperate with all payer inquiries relating to claims for laboratory services, including but not limited to, questions concerning coverage and medical necessity.

Medicare National and Local Coverage Determinations

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 https://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx.
CMS' Medicare Access Contractors (MACs) and fiscal intermediaries have published Local Coverage Determinations (LCDs) for certain laboratory tests. Laboratory tests that do not meet applicable NCD or LCD coverage requirements are considered "non-covered 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) requires 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. As we often 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

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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.

Patient Requests for Test Results

In 2014, federal regulations were changed to allow patients to obtain their test results directly from a laboratory. For testing performed by PathGroup, we are required to provide a copy of any patient test reports within thirty (30) days of the date on which a patient makes the request in writing. However, we will not explain the results of any such report to a patient as any explanation should come from the patient's treating physician.

Informed Consent

Some state laws require physicians ordering genetic testing and/or releasing such test results to obtain informed consent from the patient (or legally authorized representative). Although the requirements vary by state, typically, these requirements relate to hereditary or germline cancer tests. It is the treating physician's responsibility to be knowledgeable of all state laws and/or regulations regarding the appropriate disclosure and documentation necessary for obtaining a patient's informed consent.

Requisition Requirements

In addition to having a patient diagnosis indicating the medical necessity for testing (in ICD-10 or narrative description format), each PathGroup requisition form must also 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 PathGroup requisition forms that indicate that PathGroup should bill a third party payer, please also include a copy of the patient's insurance card with each requisition form. If PathGroup receives a test order on a non-PathGroup requisition form or an incomplete requisition form, processing of your test order may be delayed.

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. For your convenience, a listing of all specimen requirements may be found on our website at https://www.testmenu.com/PathGroup/TestDirectory/SiteFile?fileName=sidebar%5CScopeofServices2017FINAL.pdf

Verbal Test Orders

Medicare regulations require that all orders for laboratory tests be in writing. If a physician 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, PathGroup will send a confirmation of the verbal order request to the ordering physician, requesting it to be signed and sent back to the laboratory for its records. Testing will not be performed until the signed confirmation or a properly completed PathGroup requisition form is returned to the laboratory.

Pre-Authorization

Payers may have pre/prior authorization requirements in place for certain laboratory tests. Clients agree to assist PathGroup in obtaining all pre-authorizations required by third-party payers in a timely manner.

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Billing Information and Client Billing

PathGroup will, whenever possible and permitted by law, directly bill and collect from all insurers, including health care service plans (e.g., health maintenance organizations), federal and state health care programs (e.g. Medicare and Medicaid), and other third party payers unless a client indicates that it should otherwise be billed on the PathGroup requisition form, or a client has, as permitted by law, a contract with PathGroup providing for a 100% client bill arrangement.

Patient Billing Policy

Clients are advised that patients will receive invoices from PathGroup for deductibles, co-insurance, and co-payments as required by their insurance provider. If PathGroup is an out-of-network laboratory and the payer makes payment directly to a patient for the lab services PathGroup performs, PathGroup must invoice the patient for such services to obtain payment. In situations in which PathGroup is an in-network provider, PathGroup is contractually obligated to invoice patients for any co-payment, co-insurance or deductible that a payer determines is the patient's responsibility. Under HIPAA, patients may opt out of using their insurance benefits in order to prevent reporting this service to their insurance carriers. PathGroup must be informed at the time of ordering, for each order, if the patient is choosing a "patient self pay" option. The patient will be billed at patient self pay rates for the testing services performed. Patients are encouraged to contact the PathGroup Customer Service Billing Department at 855.627.4002 if they believe there is a billing error, need to coordinate payment arrangements or have questions about their bill. 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 PathGroup, any of our pathologists may, in their discretion as the interpreting pathologist, order additional reflex tests on a specimen based on their independent medical judgment and if clinically indicated for the patient. In such cases, the PathGroup interpreting pathologist will use commercially reasonable efforts to contact the ordering physician to discuss the case before ordering the reflex testing. Our discretionary authority to order reflex testing only applies to cases in which PathGroup is performing the Professional Component interpretation and such reflex testing is recommended by the reviewing pathologist.

Reflex Standing Orders and Custom Panels

The Office of Inspector General for the Centers for Medicare and Medicaid Services has stated that using a customized panel may result in the ordering of tests which are not covered, reasonable or necessary. As such, the ordering healthcare provider must review and renew annually via signature to confirm the continued medical necessity of all tests in requested custom panel(s).

Ordering healthcare providers may request standing orders, including reflex standing orders, via written request to the laboratory. The ordering healthcare provider must review and renew annually via signature for continuation of such standing orders.

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Client Requests for Performance Data

In the event that a regulatory body or certification agency requests test performance and/or quality assurance (QA) data for tests we have performed on a client's behalf, we will use commercially reasonable efforts to provide such information. All requests should be submitted through our Client Services Department and include the exact information required, including any applicable instructions from the regulatory body or certification agency requesting the data. Please allow thirty (30) days to process your request.

De-Identified Test Data

From time to time, we make de-identified test result data available to pharmaceutical companies and other entities engaged in healthcare research. In accordance with applicable regulations under the Health Information Privacy and Accountability Act ("HIPAA"), we are permitted to de-identify protected health information ("PHI") and provide such de-identified information to third parties. None of the data we provide to third parties contains any PHI protected under HIPAA.

Patient Information

Patients may: Obtain a copy of their paper or electronic health record, ask PathGroup to limit the information PathGroup shares, request confidential communication, amend their health record, obtain a list of those with whom PathGroup has shared patient information, obtain a copy of this privacy notice, file a complaint if the patient believes their privacy rights have been violated, and/or be notified by PathGroup of any changes to our health information practices.

Inducements

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce or reward 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 and should be reported to the PathGroup by calling 615.221.4455.

Prohibited Referrals

It is the policy of PathGroup to comply with all aspects of the laws and regulations governing physician self-referral, most notably including the federal Stark law (also known as the physician self-referral 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.

Financial Assistance Programs

PathGroup 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. PathGroup is committed to delivering the best patient care to all, and to meet this objective has established a financial support program. This financial support program helps ensure affordable access to PathGroup's services. Patients with special financial needs may be eligible for support to help defray some of PathGroup's testing costs. PathGroup encourages those patients who may not be able to pay fully for PathGroup's services to contact PathGroup at 888.627.4002 for an assessment of eligibility for financial support in accordance with federal guidelines.

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Laboratory Services Provided To Hospitals and Skilled Nursing Facilities

When a hospital obtains laboratory tests for hospital outpatients under arrangements with a clinical laboratory, only the hospital can bill for the arranged services that are provided to Medicare beneficiaries. Medicare Claims Processing Manual, CH. 16, Sec. 40.3. Under the Medicare Outpatient Prospective Payment System ("OPPS"), payment for clinical diagnostic laboratory tests provided to hospital outpatients is generally packaged into the payment for the outpatient procedure performed. Similarly, under the Medicare Inpatient Prospective Payment System ("IPPS"), payment for clinical diagnostic laboratory tests provided to hospital inpatients is packaged into the DRG payment for the admission. Similar payment packaging policies may apply during a Medicare patient's stay in a Skilled Nursing Facility ("SNF"). If you are ordering PathGroup services for a hospital patient or a SNF resident, please notify PathGroup to ensure that the services are appropriately billed.

Supplies

PathGroup provides supplies and materials to ordering physicians only to the extent that such items are necessary and directly related to the collection, preservation, transport or storage of specimens for which tests are being ordered from our laboratory. In addition, such items are provided only if there are assurances that they are in fact being used for these limited purposes only. PathGroup tracks the amount of supplies provided to your office and compare that number to the number of specimens sent to PathGroup at the client level in order for excessive and/or improper ordering or use of supplies to be prevented. If you have any questions regarding your supply orders, please contact your laboratory representative.

Sincerely,

Ben W. Davis, MD
President and Chief Executive Officer

Daniel A. Valenti
Executive Vice President, Chief Administration and Information Officer