
Annual Notice to Physicians **2025**

The Office of Inspector General (OIG) recommends clinical laboratories send annual notices to physicians to advise them of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services. This Annual Notice is provided pursuant to that recommendation.

Medical Necessity:

Three Rivers Diagnostics' requisition form is designed to ensure that the physician or other authorized individual has made an independent medical necessity decision regarding each test the laboratory will bill. The OIG recognizes that a provider has the option to order any tests that they think is appropriate for treatment. However, Medicare may deny payment for a test that the physician believes is appropriate, but which does not meet the Medicare necessary coverage criteria or where documentation in the entire patient record, including that maintained in the physician's records, does not support that the tests were reasonable and necessary for a given patient. Please be aware that any provider who orders medically unnecessary tests for which Medicare reimbursement is claimed, may be subject to civil penalties under the False Claims Act.

Per Medicare, all eligible medical providers must be enrolled with Medicare as an approved or opt-out status to order/refer items for Medicare beneficiaries. Even if the medical provider does not submit claims to Medicare for their own services provided, they must enroll in Medicare for the sole purpose of referring/ordering. If claims are returned to the laboratory as non-payable, we will reach out to inform you of the issues and request you enroll in Medicare so the services being rendered are covered.

Medicare National and Local Coverage Determinations

Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) specify tests that have limited coverage under Medicare and list covered diagnosis codes for these tests. LCDs and NCDs can be viewed at <https://www.cms.gov/medicare-coverage-database/>.

Diagnosis information (ICD-10 codes) must be submitted for all tests ordered, as documentation of the medical necessity of the service. Medicare generally does not cover routine screening services.

Test Ordering:

If you are not submitting orders electronically, please use the laboratory requisition preprinted with your clinic information provided to you by Three Rivers Diagnostics. Provide the following information on all requisition forms; patient name, DOB, gender, address, insurance carrier, policy number, DOI (if applicable), collection date, diagnosis code(s), prescribed medication(s), desired test(s), patient's signature, ordering provider's signature. In addition, each sample must be labeled with two forms of unique patient identifiers.

If Three Rivers Diagnostics receives an incomplete requisition form, there may be a delay in the processing of your sample. As necessary, Three Rivers Diagnostics will contact your clinic to obtain any missing information and/or clarify each specific test being ordered with the ordering provider.

Medicare regulations require that all orders for laboratory tests be in writing. If a physician or authorized individual 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, Three Rivers Diagnostics 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.

Anti-Kickback, Stark Law, False Claims Act

Three Rivers Diagnostics complies with all aspects of the Anti-kickback Statute, which prohibits the exchange of remuneration. Federal law prohibits offering or paying any remuneration to induce the referral of tests that are covered by Medicare, Medicaid, or other federal health care programs. Three Rivers Diagnostics does not offer any inducements to clients. All supplies and equipment provided to clients are directly related to specimen collection, processing, and shipping of samples.

Three Rivers Diagnostics complies with all aspects of the laws and regulations governing physician self-referral, including Stark Law. The Stark law's self-referral ban states that if a financial relationship exists between a physician (or immediate family member) and a laboratory, and the relationship does not fit into one of the law's exceptions, then (1) a physician may not refer Medicare patients to the laboratory, and (b) the laboratory may not bill Medicare for services referred by the physician.

Three Rivers Diagnostics complies with all aspects of the Federal Civil False Claims Act (FCA), which protects the Federal Government from being overcharged or sold substandard goods or services. The civil FCA imposes civil liability on any person who knowingly submits, or causes the submission of a false or fraudulent claim to the Federal Government. Under the criminal FCA, 18 U.S.C. Section 287, individuals or entities may face criminal penalties for submitting false, fictitious, or fraudulent claims, including fines, imprisonment, or both.

CPT Codes:

Upon request, Three Rivers Diagnostics can provide CPT codes that are used for billing.

Patient Billing Policy:

Insured patients are billed deductibles, co-insurance and co-payments as required by their insurance provider. Three Rivers Diagnostics offers a patient self-pay option for patients who wish to waive insurance benefits and pay a flat, out-of-pocket rate for testing services. Coverage of testing services will vary according to the type of test ordered, insurance type and patient benefits. Certain tests may not be a covered benefit for some patients due to active LCDs or other insurer coverage policies that limit benefits to narrow clinical indications. Three Rivers Diagnostics will invoice the patient and payment must be received timely. If the patient is found to have no insurance, Three Rivers Diagnostics may offer an uninsured rate.

Patients are encouraged to contact us if they believe there is a billing error, need to establish payment arrangements or have questions about their bill. To learn more, please call 412-909-4334 or visit our website <https://www.threeriversdx.com/>.