

2025 Annual Notice of Laboratory Compliance

Dear Providers/Clients,

At St. Joseph's/Candler ("SJ/C"), 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 Licensed Independent Practitioners (LIP) advising them of the elements of the laboratory's compliance program (available at: <https://oig.hhs.gov/documents/compliance-guidance/965/cpcl.html>). This letter serves as SJ/C'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 LIP supporting medical necessity before we can perform a laboratory test. CMS also requires a signed LIP order be maintained in the patient record for each test ordered or the signature of the ordering LIP 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 (NCD) for certain laboratory tests, which can be accessed on the CMS website at <https://www.cms.gov/medicare-coverage-database/search.aspx> .

Furthermore, CMS Medicare Access Contractors (MAC) 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) 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. Since we do not always have the opportunity to interact directly with patients, it is the responsibility of the ordering LIP to be familiar with applicable NCD and LCD coverage rules, including ABN requirements, to ensure that informed medical necessity determinations are made for each patient and are supported by a signed order in the patient's medical record. ABNs must accompany the order/requisition when samples are sent to the lab, prior to testing. SJ/C Laboratory will be responsible for collecting the ABN from the patient when a laboratory staff member actually collects the specimen. Please check the expiration date located in the lower left-hand corner of the ABN, to assure the most current form (Exp. 01/31/2026) is being utilized and completed, when an ABN is needed for a Medicare beneficiary. Information about ABNs may be viewed at: <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN>.

American Medical Association (AMA) defined Organ or Disease-Oriented Panels will only be paid and will only be billed when all components are medically necessary. The AMA panels and their components are listed in an attachment to this notice. Customized profiles require annual written notices signed by the LIP that explains the Medicare reimbursement paid for each component of each such profile, using a customized profile may result in the ordering of tests which are not covered, reasonable, or necessary and the tests will not be billed.

Medicare Reimbursement Fee Schedules

Medicare reimburses laboratory testing services through either the LIP 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

Clients are advised that patients will receive invoices from SJ/C 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 and are considered "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 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 LIP 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. Furthermore, SJ/C requires certain information

to enable our Billing Department to bill Medicare, Medicaid or other third-party payers. The SJ/C Laboratory requisition must contain adequate, clearly labeled spaces with the following information:

- patient's full name;
- patient's current complete address, city, state and zip code;
- date of birth and gender;
- patient's insurance company name, ID number including prefix/suffix, and a copy of the patient's CURRENT insurance card, if applicable;
- ordering/referring Provider's name and NPI number;
- valid ICD-10-CM diagnosis code(s) for each test, not just Medicare Limited Coverage Tests; and
- a valid ABN, when mandated by Medicare NCD/LCD policy.

Reflex Laboratory Tests

Reflex testing occurs when initial test results are outside normal parameters and indicate that a second related test or further testing is medically appropriate. The SJ/C Laboratory utilizes testing criteria set by government or accrediting agencies, best practices and standards of care in laboratory medicine to determine which tests are subject to reflex testing.

Physician Clinical Consultants

The SJ/C Laboratory has a professional staff of pathologists specializing in all areas of laboratory medicine. Our pathologists are available to discuss laboratory testing questions, including questions regarding ordering and interpretation. If you need to contact one of our pathologists, please call SJ/C Lab Client Services at 912.819.8440.

Thank you for using SJ/C Laboratory and 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/LIP-education/index.asp>. Also, should you have questions, please feel free to contact the SJ/C Laboratory Quality Assurance Manager at 912.819.2653 or the SJ/C Laboratory Outreach Business Manager at 912.819.2336.

Sincerely,

St. Joseph's/Candler