

ANNUAL NOTICE TO PROVIDERS

September 2024

Dear Physician/Valued Client:

Hennepin Healthcare Laboratory System is committed to complying with all guidelines set forth by the Federal Office of the Inspector General (OIG), the Center for Medicare and Medicaid Services (CMS), and the Department of Health and Human Services (HHS). As part of our compliance efforts, we are providing you with this Annual Notice which contains important information regarding the services you order for your patients.

- Federal law requires that ordering providers give diagnostic information with every test requisition.
- Physicians and other healthcare providers should only order those tests they believe are medically necessary for the diagnosis, treatment, and therapy of their patient. The medical necessity of each test ordered must be documented in the patient's medical record and reflect all coding submitted with the lab requisition.
- Organ, disease related, or HCMC Clinical Laboratories developed panels should only be ordered and billed when **all** components are medically necessary.
- The OIG takes the position that physicians or other individuals authorized by law to order laboratory tests, who knowingly cause 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. HCMC Clinical Laboratories will not knowingly bill Medicare/Medicaid for lab testing that is non-covered, unreasonable and/or unnecessary.
- CMS has developed National Coverage Determination (NCD) Policies for certain lab tests/CPT codes. In addition, National Government Services (MAC-Part B) has developed Local Coverage Determination (LCD) Policies for additional lab tests/CPT codes. Any lab test contained in one of these NCD/LCD policies must have a covered diagnosis code assigned to indicate medical necessity per Medicare rules. For a complete list of NCD/LCD policies, with test name(s), CPT and ICD-CM code(s), please review:

NCD = [MCD Reports \(cms.gov\)](https://www.cms.gov/medicare-coverage-determinations)

LCD = [Local Coverage Final LCDs by State Report Results \(cms.gov\)](https://www.cms.gov/medicare-coverage-determinations)

If a non-covered diagnosis is used the patient must be notified in advance and given the opportunity to sign the Advance Beneficiary Notice (ABN) prior to specimen collection. The ABN must be completed for any Medicare patient where claim denial

is suspected based on medical necessity or frequency determinations. The signed, original ABN must be available for review by HCMC Clinical Laboratories by request. For more information on ABN see: [FFS ABN | CMS](#)

- HCMC Clinical Laboratories has specific policies regarding REFLEX TESTING AND CRITICAL ALERT VALUES. Reflex testing is additional testing (with additional cost) that is automatically performed based on the initial results. Procedures that contain a reflexive pathway are identified in our test directory under the individual test listing. Critical Values are listed in the Resources section of our test directory. Please visit <https://www.testmenu.com/hcmc> or contact Melissa Lallak, Laboratory Administrative Director at melissa.lallak@hcmcd.org.
- Medicare Laboratory fee schedule may be found at [CLFS Files | CMS](#) Medicaid reimbursement will be equal to or less than Medicare reimbursement.
- The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC health IT Certification Program is a rule by the Health and Human Service Department published May 1, 2020. In summary, the rule requires reasonable and necessary activities that do not constitute information blocking and advance interoperability and support of the access, exchange, and use of electronic health information. This includes the immediate release of certain test results to the patient's medical record. Additional information can be found at [Federal Register :: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program](#).

For more information regarding this communication, please contact Lab Customer Service at Labcustomerservice@hcmcd.org.

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