

2016 Annual Notice to Physicians

The Office of Inspector General (OIG) recommends that clinical laboratories notify physicians and other ordering providers who use their services, at least once a year, as part of their Corporate Compliance Program. MDxHealth is issuing this annual notice in accordance with this recommendation and to inform the recipients of the laboratory's policies for test ordering and billing and provide certain other information regarding the laws and regulations that govern laboratory services.

Medical Necessity

The OIG has advised clinical laboratories to remind physicians (and other individuals authorized by law to order tests) that the Government and private third party payers will only pay for tests that are medically necessary for the diagnosis or treatment of the individual patient. It is the responsibility of the authorized ordering provider to ensure claims being submitted for payment to federally funded programs or private third party payers only occur when services are covered, reasonable and medically necessary. It is the responsibility of the provider to document each ordered test and the corresponding diagnosis information in the patient's medical record and for providing appropriate diagnostic information in the form of ICD-10 codes to the highest level of specificity or a narrative to MDxHealth. The Office of Inspector General takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties under the False Claims Act.

Medicare National And Local Coverage Determination

The Medicare Program publishes National Coverage Determinations (NCDs) and local Medicare contractors publish Local Coverage Determinations (LCDs) for certain tests. These policies define the medical conditions through the inclusion of a list of ICD-10 diagnosis codes for which these tests are covered or reimbursed by Medicare. Coverage determinations may be viewed at:

<https://www.cms.gov/medicare-coverage-database/>

An LCD (MoIDX-CDD: ConfirmMDx Epigenetic Molecular Assay (L36327)) has been issued by our Medicare contractor, Noridian Healthcare Solutions, which impacts coverage and reimbursement for the ConfirmMDx for Prostate Cancer testing services offered by MDxHealth. MDxHealth has established a Certification and Training Registry (CTR) program under the provisions of the LCD to support coverage for Medicare patients for ConfirmMDx testing. For information on physician certification and training for enrollment into the ConfirmMDx CTR, please contact MDxHealth Client Services at 866-259-5644 or client.services@mdxhealth.com. The ConfirmMDx LCD can be found through the Noridian website at:

<https://med.noridianmedicare.com/web/jeb/policies/moldx/covered-tests>

Test Ordering

A standard MDxHealth test requisition form should be used when ordering tests. If MDxHealth receives an incomplete test requisition or test order on a non-MDxHealth requisition form, processing of your test order may be delayed. As necessary, MDxHealth will contact physicians to have them resubmit the test order on a MDxHealth test requisition form or clarify the test being ordered. The test requisition is the tool used to communicate the physician order to the lab and is designed to encourage physicians to order only those tests which the physician believes are appropriate and medically necessary for the diagnosis or treatment of each patient. Upon request by MDxHealth or its payers/auditors, ordering providers are required to provide any/all chart documentation (including physician signature), that reflects the actual lab order and/or supports the authenticity and medical necessity of the lab order(s) submitted. Signature stamps are NOT acceptable. Orders must include legibly written or electronic signatures.

Medicare Laboratory Fee Schedule

MDxHealth is reimbursed under the Medicare physician fee schedule for examination and selection of retrieved archival tissues for molecular analysis and for macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies. Beneficiaries are responsible for applicable coinsurance and deductible amounts. Medicaid reimbursement will be equal to, or lesser than, Medicare reimbursement. The Medicare Physician Fee schedule can be obtained online at:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html>

Clinical Consultants

MDxHealth's Clinical Consultants are available to discuss appropriate test use, test orders and interpretation of test results. Please contact Customer Services at 866-259-5644 for assistance.

Inducements

Federal law prohibits offering or paying any remuneration – meaning anything of value – to induce 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 MDxHealth compliance hotline by calling 844-710-0003.

Prohibited Referrals

It is the policy of MDxHealth to comply with all aspects of the laws and regulations governing physician self-referral, most notably including the federal Stark 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 squarely 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.

PATIENT PRIVACY (HIPAA)

Under the Health Insurance Portability and Accountability Act (HIPAA), MDxHealth is a health care provider and a covered entity. It is our policy to comply with the letter and intent of the HIPAA privacy and security standards. Our privacy policy is available at <http://mdxhealth.com/privacy-policy>.

Financial Assistance Programs

MDxHealth 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. MDxHealth 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 MDxHealth's services. Patients with special financial needs may be eligible for support to help defray some of MDxHealth's testing costs. MDxHealth encourages those patients who may not be able to pay fully for MDxHealth's services to contact us for an assessment of eligibility for financial support in accordance with federal guidelines

If you have any questions related to this notice, please contact MDxHealth Compliance Department 866-259-5644 or compliance@mdxhealth.com.

Laboratory Director,

Jess Savala M.D