



To: All Clients
From: Compliance Department
Re: 2020 Annual Disclosure Letter
Date: September 2020

MD Labs is providing this notice in accordance with the recommendation made by the Office of Inspector General (OIG) as part of our Compliance Program. Periodically, MD Labs will advise its provider clients about program changes and information related to federally funded healthcare programs.

When ordering tests for which Medicare reimbursement will be sought, the following policies apply:

Orders are only accepted by Licensed Physicians and Non-Physician Practitioners.

A clinical laboratory may only bill Medicare and Medicaid for testing ordered by a licensed physician or other individuals authorized by law to order laboratory tests. If your license has been revoked or suspended, please immediately notify MD Labs. As of 2014, Medicare requires registration of all ordering providers to the Center for Medicare and Medicaid Services Provider Enrollment, Chain, and Ownership System (PECOS). More information on PECOS and how to enroll in the system may be viewed at <https://pecos.cms.hhs.gov/providers/index.html>

Excluded Clients

MD Labs will not accept orders for tests from any individuals or entities debarred, excluded, or otherwise declared ineligible from participation in federal or state-funded health care programs or has lost their license to provide health care services.

MD Labs will review the HHS/OIG List of Excluded Individuals or Entities database continually to ensure no existing clients are debarred, excluded, or otherwise declared ineligible from participation in federal or state-funded health care programs. MD Labs will monitor appropriate sources to ascertain whether a client has lost their license to provide health care services.

Any provider who appears on any debarred, excluded, or ineligible list will immediately receive notification of such. MD Labs cannot accept orders from any provider during a sanctioned period. MD Labs will resume accepting orders with reasonable proof that the provider has been reinstated in federal or state-funded health care programs or has had their license reinstated.

New Ordering Providers

If you should add new Ordering Providers to your practice, please reach out to your MD Labs account representative so that MD Labs can add your new medical staff member to your account.

Medicare Medical Necessity Policy

Tests that are medically necessary for the diagnosis or treatment of a Medicare patient are covered and are reimbursable. However, we cannot guarantee reimbursement from Medicare.

The OIG takes the position that physicians or other individuals authorized by law to order laboratory tests, who knowingly cause a false claim submission to any federally funded program, may be subject to sanctions or remedies available under civil, criminal and, administrative law, such as the False Claims Act. <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Fast-Facts/False-Claims>

Diagnosis Coded to Highest Level of Specificity

Section 4317 of the Balanced Budget Act of 1997 requires the physician or authorized ordering party to submit diagnosis information on the laboratory order for submission of a Medicare claim. The diagnosis information supplied needs to be coded to the highest level of specificity and accurately describe the patient's condition on the date of service, as documented in the patient's medical record. MD Labs will contact providers for all requisitions that do not include this required information, this communication may occur via telephone call, email, or fax.

2020 Medicare Clinical Diagnostic Laboratory Tests Payment System

Effective January 1, 2017, the Clinical Lab Fee Schedule (CLFS) reimbursement rates were revised to be based on the weighted median private payer rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. Co-payments and deductibles do not apply to services paid under the Medicare clinical laboratory fee schedule. Also, Medicaid reimbursement will be equal to, or lesser than Medicare reimbursement. The 2020 Medicare Clinical Laboratory Fee schedule may be viewed and downloaded at <https://www.cms.gov/medicare/medicare-fee-service-payment/clinicallabfeeschedclinical-laboratory-fee-schedule-files/20clabq1>

The Centers for Medicare and Medicaid Services has authorized Noridian, LLC, Nevada Medicare Part B carrier, to develop Local Coverage Determinations (LCD). These guidelines may supplement or be in addition to the National Coverage Determinations and give direction for medical necessity on selected tests. All laboratory LCD'S are available at <https://med.noridianmedicare.com/web/jeb/policies>

Advance Beneficiary Notice of Noncoverage (ABN)

Medicare does not cover all laboratory services. An Advance Beneficiary Notice of Noncoverage (ABN) is one of the most critical Medicare forms you can utilize. Medicare states it must be made available to the patient when Medicare does not consider an item or service to be reasonable and necessary according to the patients' diagnosis or Medicare Policy.

Examples of everyday situations where an ABN is needed, include when the test ordered:

- Is considered experimental, investigational, or research only.
- Is not indicated for the diagnosis or treatment of the patient.
- Exceeds the frequency of services allowed for a specified period for the corresponding diagnosis.

A new ABN form needs to be signed for each encounter. The ABN is proof that the patient received notification that Medicare payment is expected to be denied for their laboratory services. As an informed consumer, the patient can then decide whether to accept the laboratory services as an out-of-pocket expense or through other insurance if available.

June 2020 Update: The ABN, Form CMS-R-131, and instructions have been revised. The revised form can be used immediately and becomes mandatory on August 31, 2020. There are quite a few changes to the instructions. See attachment; note that the new form has an expiration date of July 30, 2023, at the bottom of the form.

MD Labs Policy

MD Labs will not bill Medicare patients for laboratory testing that Medicare has determined is not "reasonable and necessary" unless the patient has signed an ABN before the collection of the specimen for the laboratory testing being ordered. Please visit our website at MDLabs.com/BillingResources for an ABN Form. Information about ABNs can be viewed at <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN>

Billing Information

MD Labs requires the following information to enable our Billing Department to bill Medicare, Medicaid, or other commercial insurance. This information can either be provided on the MD Labs requisition form or included on enclosures to the requisition form.

- The patient's full name, date of birth, gender, and address. A copy of the patient's face sheet or lab requisition order with this information can be provided instead of including the information on the Requisition form.
- Insurance information, including insurers name, address and phone number. A copy of the lab requisition order with this information, or a copy of the insurance card (front and back) can be provided instead of including the information on the Requisition form.
- Ordering provider's name and NPI number.
- Valid ICD-10-CM diagnosis code(s) defined to the highest level of specificity, for each test ordered to confirm medical necessity.
- Valid ABN, when mandated by Medicare NCD/LCD policy.

Billing Information SARS-CoV-2 (COVID-19)

MD Labs has developed a multiplex RT-PCR test that quickly and accurately identifies a COVID-19 infection. Our laboratory operates under the quality standards of the FDA, CAP, and CLIA. **The following patient demographics are required and must be submitted with each specimen:**

- Patient Name
- Date of Birth
- Street Address (cannot be PO Box)
- County
- Race and/or ethnicity

The ordering provider must also agree to comply in a timely manner with any requests for medical documentation required for the adjudication of MD Labs claims.

Compliance with Federal Beneficiary Inducement Statute, Anti-Kickback Statute, Stark Law and EKRA

It is MD Labs policy to fully comply with the Medicare Beneficiary Inducement Statute, Anti-Kickback Statute (AKS), Stark Law and Eliminating Kickback in Recovery Act (EKRA). MD Labs prohibits its employees from offering or providing remuneration to clients or patients to induce or influence a physician, non-physician practitioners, and other types of clients to refer that patients' testing to MD Labs.

The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include— (A) the waiver of coinsurance and deductible amounts by a person, if (i) the waiver is not offered as part of any advertisement or solicitation; (ii) the provider does not routinely waive coinsurance or deductible amounts; and (iii) the provider (a) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or (b) fails to collect coinsurance or deductible amounts after making reasonable collection effort.

<https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>

<https://www.congress.gov/bill/115th-congress/senate-bill/3254/text>

<https://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf>

Reflex Testing

MD Labs offers three types of reflex testing: (i) reflex tests required by law, (ii) standard reflex tests, and (iii) client-specific reflex tests. Reflex testing required by law occurs whenever an initial test is positive or outside normal parameters, and state or federal law requires the performance of a second related test. An example of a reflex test required by law is the FTA test when a VDRL is positive. Reflex tests that are required by law in conjunction with the initial test are documented on the MD Labs test requisition.

Add-on Testing

To verbally request additional tests to be added to an existing order, please call MD Labs Customer Service at **775-391-5221 option 6** and a MD Labs representative will verify the specimen is available and adequate for testing. You will then be instructed to fax a new order for the tests you are adding to our Customer Service Department at **775-737-9133**. This additional order needs to be maintained in the patient's medical record. If MD Labs does not receive the signed add-on order request form promptly, it may cause a delay in reporting. Written verification for add-on test requests is required by our accrediting agency, the College of American Pathologists.

Test Cancellations

MD Labs will honor test cancellation requests submitted before test completion. If the cancellation request is received after the specimen has been analyzed, and the result has been produced, the request cannot be honored, and the usual test charge will be assessed.

Contracted Payers

MD Labs is a Medicare, Medicaid, and Military certified lab that provides and participates as an in-network facility with Medicare Advantage Programs as well as Managed Medicaid Programs. We are in acceptance of National, Regional, and State commercial Managed Care Organizations, Federal/State Employee Medi-Gap, and Employer/TPA programs.

Fee Schedules

Our list price fee schedule, which is 1x to 2x of Medicare Expect Price, and our self-pay fee schedule for uninsured or under-insured patients are attached for your reference. The effective date of the self-pay fee schedule is October 1, 2020. Prices are subject to change without notice.

Financial Assistance Program

Only at a client's request and when the client offers a similar discount or waiver of their own charges or fees will MD Labs agree to provide testing for that client's needy patients at a reduced cost. MD Labs Compliance Officer reviews and monitors all Requests for Financial Assistance. For your convenience, a copy of our Financial Assistance Policy as well as the Application for Financial Assistance are located on our Website at MDLabs.com/BillingResources.

Are you in Compliance with CMS Rules? (Noridian CMS)

For any services to be covered by Medicare, the patient's medical record must contain sufficient documentation to support the need. This should include the patient's diagnosis and other pertinent information, such as the duration of the patient's medical condition, clinical course (worsening or improvement) prognosis etc.

Your cooperation is a legal requirement as outlined in the Social Security Act. The law governing Medicare Section 1842(p)(4) of the Act mandates that:

In case of an item or service...ordered by a physician or practitioner...but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic and or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time the item or service is ordered by the physician or practitioner. (Attached is the letter from Noridian Healthcare Solutions, MD Labs Medicare Part B Intermediary)

Requests for Additional Information

MD Labs will provide Requests for Additional Information on a weekly basis as needed, the missing or incomplete information will be clearly identified on the MD Labs Request for Additional Information Form. Our form is an editable pdf document, so please type the information directly onto the report. Diagnosis Codes must be coded to the highest level of specificity for the laboratory test(s) ordered and require the Ordering Practitioner's signature.

Send completed requests to:

- FAX to: **775-499-5146** Attn: Billing
- Mail to: MD Labs 10715 Double R Blvd, Ste. 102 Reno, NV 89521 Attn: Billing

Should you have any questions or concerns please call our Billing Department at **775-499-5150**.

Customer Service

Customer service representatives are available 6am to 6pm PST, seven days a week at **775-391-5221 option 6**.

Included with this letter are the following policies, forms, and documents:

- MD Labs Annual Disclosure Letter
- Required Acknowledgement and Confirmation Statement of Medical Staff within your practice with NPI numbers
- Postage Paid Return Envelope
- MD Labs Self-Pay Fee Schedule
- MD Labs Financial Assistance Program
- MD Labs Application for Financial Assistance
- Are you in compliance with CMS rules? (Noridian MAC)
- Advance Beneficiary Notice of Noncoverage (ABN) Instruction
- ABN Form (English and Spanish)
- MD Labs Request for Additional Information Form and Instructions

Additionally, annually during the 1st quarter of each year, your office will receive an Annual Disclosure Letter and supporting documents from MD Labs, if you do not receive these documents please notify your MD Labs account representative.

Please take a minute to review this information with your appropriate staff. We value your staff and patients and appreciate the opportunity to serve your laboratory needs in conjunction with these initiatives. A copy of this 2020 Annual Disclosure Letter is located on our website at MDLabs.com/BillingResources. If you have further questions regarding this information, please contact your MD Labs account representative.

Kind Regards,

MD Labs