MDHHS Michigan Department of Health & Human Services

Medical Services Administration

BULLETIN MSA

Bulletin Number: MSA 20-52

Distribution: Practitioners, Pharmacies, Outpatient Hospitals, Local Health Departments, Federally Qualified Health Centers, Rural Health Clinics, Independent Diagnostic Laboratories, Medicaid Health Plans, Integrated Care Organizations

Issued: July 31, 2020

Subject: COVID-19 Response: COVID-19 Test Ordering and Pharmacy Enrollment

Effective: May 26, 2020

Programs Affected: Medicaid, Healthy Michigan Plan, Children's Special Health Care Services, Maternity Outpatient Medical Services, MI Health Link

Per Centers for Disease Control and Prevention (CDC) and State recommendations, widespread diagnostic testing for COVID–19 is a critical component of a public pandemic response to support infection control and proper treatment. These policy changes enable additional qualified medical professionals the ability to order vital COVID-19 testing services at a community testing location and enable pharmacies to enroll as an independent clinical laboratory to perform COVID-19 laboratory tests.

Consistent with public health emergency conditions at both the state and federal level related to COVID-19, the Michigan Department of Health and Human Services (MDHHS) is issuing this policy effective May 26, 2020.

Ordering COVID-19 Laboratory Tests

Consistent with State Executive Order (EO) 2020-104, to help prevent the further spread of COVID-19, Medicaid will enable a broader range of qualified medical professionals to order COVID-19 tests. **These ordering flexibilities are intended to be temporary and are effective for dates of service on or after May 26, 2020. MDHHS will notify providers of its termination.**

Pharmacists may order COVID-19 laboratory tests at community testing locations as defined in the E.O. Pharmacists must be enrolled within Medicaid's Community Health Automated Medicaid Processing System (CHAMPS). The pharmacist's name and individual National Provider Identifier (NPI) must be reported in the Ordering Provider field of laboratory claims when applicable.

Registered Nurses (RNs) and Licensed Practical Nurses (LPNs) may also initiate the ordering of COVID-19 tests for beneficiaries seeking services at community testing locations.

Claims for COVID-19 testing initiated by these professionals must contain the name and individual NPI of the supervising Medicaid enrolled physician or non-physician practitioner in the Ordering Provider field when applicable.

Providers should utilize the COVID-19 testing guidelines in accordance with CDC and Specimen Collection and Testing prioritization criteria specified by the MDHHS Chief Medical Executive when referring beneficiaries for laboratory testing. The latest information is available at www.michigan.gov/Coronavirus and www.CDC.gov/Coronavirus.

Enrollment of Pharmacies as Independent Clinical Laboratories

To provide additional laboratory resources to meet the urgent need to increase COVID-19 testing capability, pharmacies may enroll with Medicaid as Independent Clinical Laboratories. This policy is effective **for dates of service on or after May 26, 2020. The enrollment of pharmacies as independent clinical laboratories is a permanent policy change and does not expire following the termination of the public health emergency conditions.**

Pharmacies are required to obtain the appropriate Clinical Laboratory Improvement Amendments (CLIA) certificate prior to initiating enrollment. Questions regarding CLIA certification should be addressed to the state licensing agency.

Michigan Department of Licensing and Regulatory Affairs (LARA)
BCHS – Laboratory Improvement Section
P.O. Box 30664, Lansing, MI 48909
Phone: (517) 241-2648, Email: BCHS-CLIA@michigan.gov

Pharmacies that are not currently enrolled with Medicaid must complete an online application in CHAMPS. Pharmacies already enrolled with Medicaid can initiate laboratory billing privileges by modifying their current CHAMPS enrollment. Pharmacies will need to add the "*Clinical Laboratory"* Specialty and applicable CLIA certificate information to their CHAMPS record. Once modifications are approved, the pharmacy may begin submitting claims for laboratory services utilizing the professional claim format.

All providers that submit laboratory claims must report their CLIA number on claims. Pharmacies are limited to billing the laboratory services that they are CLIA certified to perform.

COVID-19 Laboratory Testing Coverage Reminder

Per Section 1905(a)(3)(B) of the Social Security Act, Medicaid coverage includes in vitro diagnostic products (as defined in Food and Drug Administration (FDA) regulations at 21 C.F.R. § 809.3(a)) for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) or diagnosis of COVID-19, and the administration of such in vitro diagnostic products. Medicaid coverage of COVID-19 in vitro diagnostic products includes both viral and antibody laboratory tests.

Healthcare Common Procedure Coding System (HCPCs) codes representative of COVID-19 testing are:

- U0001 - CDC 2019 novel Coronavirus (2019-nCoV) real-time RT-PCR diagnostic panel
- U0002 - 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC
- U0003 - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R
- U0004 - 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R
- 86328 - Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
- 86769 - Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])
- 87635 - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique

Laboratory tests must be administrated in accordance with federal CLIA regulations. Additionally, per the March 23, 2020 MDHHS Emergency Order pursuant to MCL 333.2253, all CLIA certified laboratories in Michigan are required to comply with prioritization criteria as promulgated by MDHHS. This includes public health, commercial, and healthcare facility laboratories. Laboratory providers must also comply with all COVID-19 reporting requirements issued by MDHHS.

Fee screen information is maintained on the appropriate database or fee schedule on the MDHHS website at www.michigan.gov/medicaidproviders >> Billing and Reimbursement >> Provider Specific Information. Additional pertinent coverage parameters are accessible via the Medicaid Code and Rate Reference tool within CHAMPS at https://sso.state.mi.us >> External Links >> Medicaid Code and Rate Reference.

This information is provided in addition to MDHHS guidance released on March 17, 2020, in numbered letter L 20-16 (www.michigan.gov/medicaidproviders >> Policy, Letters & Forms >> Numbered Letters >> 2020) and on April 1, 2020 in bulletin MSA 20-17 (www.michigan.gov/medicaidproviders >> Policy, Letters & Forms >> Michigan Medicaid Approved Policy Bulletins >> 2020).

Public Comment

The public comment portion of the policy promulgation process is being conducted concurrently with the implementation of the change noted in this bulletin. Any interested party wishing to comment on the change may do so by submitting comments to Adriena Krul-Hall via e-mail at:

E-mail: KrulHallA@michigan.gov

Please include “COVID-19 Response: COVID-19 Test Ordering and Pharmacy Enrollment” in the subject line.

Comments received will be considered for revisions to the change implemented by this bulletin.

Manual Maintenance

Retain this bulletin until applicable information is incorporated into the Medicaid Provider Manual. Some information is time-limited and will not be incorporated into any policy or procedure manuals.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Typical Providers may phone toll-free 1-800-292-2550. Atypical Providers may phone toll-free 1-800-979-4662.

Approved

Kate Massey, Director
Medical Services Administration