Michigan Department of Health and Human Services
Program Policy Division
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Lansing MI 48909

Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

May 18, 2017

<Provider Name>
<Provider Address 1>
<Provider Address 2>
<Provider City> <State> <zipcode5-zipcode4>

Dear Medicaid Provider:

RE: FDA Issues Safety Warning About Magellan LeadCare® Analyzers with CDC Recommendations

The purpose of this letter is to notify all currently enrolled Medicaid providers about a U.S. Food and Drug Administration (FDA) alert issued on May 17, 2017, regarding inaccurate blood lead level testing results. Certain lead tests manufactured by Magellan Diagnostics may provide inaccurate results for some children and adults. Data indicates that Magellan Diagnostics' lead tests, when performed on blood drawn from a vein, may provide results that are lower than the actual level of lead in the blood. The FDA believes the issue may date back to 2014. The warning includes the following Magellan Diagnostics' lead testing systems:

- LeadCare®
- LeadCare® II
- LeadCare® Plus
- LeadCare® Ultra

The FDA is warning laboratories and health care professionals that they should not use any Magellan Diagnostics' lead tests with blood drawn from a vein. At this time, the safety alert does not apply to capillary blood lead test results collected from a finger stick or heel stick. The Centers for Disease Control and Prevention (CDC) recommends that health care professionals retest blood lead levels for:

- **Children younger than six years (72 months) of age** at the time of the alert if their test was conducted using blood drawn from a vein using any Magellan Diagnostics' lead testing systems and received a result of less than 10 micrograms per deciliter, and
- **Women who are currently pregnant or nursing** and were tested using blood drawn from a vein using any Magellan Diagnostics' lead testing systems while pregnant or nursing.

For future blood lead testing and retesting, health care providers and public health officials should:

- Send venous samples to Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratories using inductively coupled plasma mass spectrometry (ICP-MS) or graphite furnace atomic absorption spectrometry (GFAAS) (also known as electrothermal atomic absorption spectrometry [ETAAS]) instruments.
- Send capillary samples to CLIA-compliant laboratories using any CLIA compliant analyzer including ICP-MS, GFAAS, or LeadCare® analyzers.

Federal regulations require state Medicaid Programs to offer Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services, including blood lead level testing of Medicaid children:

- At 12 and 24 months of age, or
- Between 36 and 72 months of age if not previously tested for blood lead.

A blood lead risk assessment must also be performed during specific well child visits, with follow up blood lead level testing performed when indicated. **Blood lead retesting performed in response to the FDA alert is covered as a Medicaid EPSDT service.**

Additional resources can be found at:

- CDC Health Alert Network Notification
- https://www.cdc.gov/nceh/lead/
- https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm
- https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm558769.htm

Any questions regarding this letter should be directed to Provider Support, Michigan Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mail at ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, and phone number so you may be contacted if necessary. Providers may phone toll-free 1-800-292-2550. For beneficiaries enrolled in a Medicaid Health Plan (MHP), providers may contact the beneficiary's MHP for additional assistance if needed.

Sincerely

Chris Priest, Director
Medical Services Administration