Network Notification

Date: **October 23, 2017**
To: **Kentucky Medicaid Health Partners**
From: **Humana – CareSource**
Subject: **Blood Lead Testing Recommendations**

Summary
The U.S. Food and Drug Administration (FDA) issued a safety communication warning about the use of Magellan Diagnostics' LeadCare® analyzers (LeadCare, LeadCare II, LeadCare Ultra and LeadCare Plus) with venous blood samples because they might result in falsely low test results. The FDA now advises that Magellan Diagnostics' LeadCare analyzers should no longer be used with venous blood samples. The safety alert does not apply to capillary blood lead test results collected by finger prick or heel prick. The purpose of this health advisory is to notify state and local health departments, health care providers and laboratories about Centers for Disease Control and Prevention (CDC) retesting guidance in light of the safety alert.

Background
The CDC was contacted on April 24, 2017, by the FDA, requesting assistance in assessing the potential public health risk of a negative bias associated with Magellan's lead testing systems. The FDA now warns that Magellan Diagnostics' LeadCare analyzers should no longer be used with venous blood samples due to the potential for falsely low test results. Not all blood lead tests are affected. Laboratory tests analyzed by inductively coupled plasma-mass spectrometry (ICP-MS) or graphite furnace atomic spectrometry (GFAAS, also known as electrothermal atomic absorption spectrometry [ETAAS]) are not expected to result in falsely low results. This safety alert applies to venous blood lead tests conducted using Magellan Diagnostics' LeadCare analyzers whether the patient is a child or an adult. At this time, the safety alert does not apply to capillary blood lead test results collected by finger prick or heel prick using Magellan Diagnostics' LeadCare analyzers. Children are particularly vulnerable to lead exposure due to the effect on their developing brains and organ systems. CDC is working with public health officials throughout the United States to determine where the analyzers were used and which blood lead test results might be affected.

Recommendations
The CDC recommends that health care providers retest patients who:

1) Are younger than 6 years (72 months) at the time of the alert (May 17, 2017)
2) Had a venous blood lead test result of less than 10 micrograms per deciliter (µg/dL) analyzed using a Magellan Diagnostics' LeadCare analyzer at an onsite (e.g., health care facility) or offsite laboratory.

The CDC also recommends health care providers retest currently pregnant or lactating women who had a venous blood lead test performed using a Magellan Diagnostics' LeadCare analyzer.

The CDC recommends that parents discuss retesting with their health care provider or health department to determine if their child's blood should be retested. If retesting indicates blood lead levels in excess of the CDC reference level (www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm) or the state or local action level, the health care provider or public health official should refer to CDC and/or local guidelines for appropriate follow-up action (www.cdc.gov/nceh/lead/acclpp/actions_blls.html). Retests are not recommended if the provider is certain that analyzers other than those described by this health advisory were used to analyze the venous blood samples.

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

- Send venous samples to Clinical Laboratory Improvement Amendments (CLIA)-compliant laboratories using ICP-MS or GFAAS, also known as ETAAS instruments.
- Send capillary samples to CLIA-compliant laboratories using CLIA compliant analyzers, including ICP-MS, GFAAS or LeadCare analyzers.

For more information

CDC's Lead Poisoning Prevention Program: https://www.cdc.gov/nceh/lead/
CDC's Lead and Multi-element Proficiency Program: https://www.cdc.gov/labstandards/lamp.html

Reference

FDA safety communication warning, May 17, 2017. Available at https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm558733.htm