DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

REVISED product from the Medicare Learning Network® (MLN)

- **"Medicare Enrollment Guidelines for Ordering/Referring Providers"** Fact Sheet (ICN 906223), downloadable

MLN Matters® Number: MM8805 Revised **Related Change Request (CR) #: CR 8805**

Related CR Release Date: September 17, 2014 **Effective Date: : October 1, 2014**

Related CR Transmittal #: R3070CP **Implementation Date: October 6, 2014**

New Waived Tests

Note: This article was revised on September 19, 2014, to reflect the revised CR8805 issued on September 17. The article was revised to correct the description in bullet point 7 on page 2. Also the CR release date, transmittal number, and the Web address for accessing the CR are revised. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratory providers submitting clinical diagnostic laboratory claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

Provider Action Needed

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

The Current Procedural Terminology (CPT) codes that the Centers for Medicare & Medicaid Services (CMS) consider to be laboratory tests under CLIA (and thus requiring certification) change each year. Change Request (CR) 8805 informs the MACs about the latest new CPT codes that are subject to CLIA edits. Make sure your billing staffs are aware of these latest CLIA-related changes, and that you remain current with certification requirements.

Background

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The CPT codes for the following new tests must have the modifier QW (CLIA-waived test) to be recognized as a waived test. However, the tests mentioned on the first page of the list attached to CR8805 (i.e., CPT codes: 81002, 81025, 82270, 82272, 82962, 83026, 84830, 85013, and 85651) do not require a QW modifier to be recognized as a waived test.

The CPT code, effective date and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

- G0434QW, September 6, 2013, BTNX Inc. Rapid Response Multi-Drug Urine Test Cup;
- G0434QW, September 6, 2013, BTNX Inc. Rapid Response Multi-Drug Urine Test Panel;
- G0434QW, October 4, 2013, uVera Diagnostics, Inc. CR2 Multi-Drug Urine Test Cup;
- G0434QW, October 4, 2013, uVera Diagnostics, Inc. CR3 Multi-Drug Urine Test Cup;
- G0434QW, October 4, 2013, uVera Diagnostics, Inc. SMARTOX U3 Multi-Drug Urine Test Cup;
- G0434QW, October 24, 2013, American Institute of Toxicology, Inc., AIT Laboratories Drug of Abuse Cup;
- 80061QW, 82962, 82465QW, 83718QW, 84478QW, November 12, 2013, Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System (LipidPlus Lipid Profile test strips);
- G0434QW, December 4, 2013, Nobel Medical Inc. INSTA-SCREEN Multi-Drug Urine Test Cup;
- G0434QW, December 5, 2013, Micro Distributing II, LTD One Step Multi-Drug Urine Test Panel;
- G0434QW, February 11, 2014, Alfa Scientific Designs, Inc. Confidential Drug Test – Multi Drugs of Abuse Urine Test (OTC);

- 87880QW, February 18, 2014, BD Veritor System for Rapid Detection of Group A Strep (direct from throat swab);
- 85018QW, February 18, 2014, Clarity HbCheck Hemoglobin Testing System;
- 87077QW, February 18, 2014, Jant Accutest Rapid Urease test (H. pylori detection);
- G0434QW, March 13, 2014, UCP Biosciences, Inc. UCP Multi-Drug Test Key Cups;
- 83986QW, March 18, 2014, RightBio Metrics, RightSpot Infant pH Indicator;
- 83986QW, March 18, 2014, RightBio Metrics, RightSpot pH Detector;
- 83986QW, March 18, 2014, RightBio Metrics, RightSpot pH Indicator;
- 85018QW, March 21,2014, AimStrip Hb Hemoglobin (Hb) Testing System;
- G0434QW, April 11, 2014, PTox Drug Screen Cup {Cassette Dip Card format};
- 86308QW, April 22, 2014, Polymedco Polystat Mono {whole blood};
- 82274QW, G0328QW, April 22, 2014, Rapid Response(TM) FIT-Fecal Immunochemical Test;
- 84443QW, May 16, 2014, Germaine Laboratories, Inc. AimStep Thyroid Screen {whole blood};
- 82055QW, May 21, 2014, Express Diagnostics International, Incorporated Saliva Alcohol Test;
- 83037QW, May 22, 2014, BIO-RAD in2it (II) System Analyzer Prescription Home Use; and
- 87880QW, May 23, 2014, Accustrip Strep A {Specimen type (Throat Swab)}.

You should be aware that your MAC will not search their files, to either retract payment or retroactively pay claims; however, they should adjust such claims that you bring to their attention.

Additional Information

The official instruction, CR8805, issued to your MAC regarding this change is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3070CP.pdf** on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** under - How Does It Work.