DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Revised product from the Medicare Learning Network® (MLN)

- **ICD-10-CM/PCS Billing and Payment Frequently Asked Questions,** Fact Sheet (ICN 908974)

MLN Matters® Number: MM9261	**Related Change Request (CR) #: CR 9261**
Related CR Release Date: August 14, 2015	**Effective Date: October 1, 2015**
Related CR Transmittal #: R3327CP	**Implementation Date: October 5, 2015**

New Waived Tests

Provider Types Affected

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

Provider Action Needed

CR9261 the MACs about the new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Since these tests are marketed immediately after approval, the Centers for Medicare & Medicaid Services (CMS) must notify its MACs of the new tests to allow MACs to accurately process claims.

CLIA regulations require a facility to be appropriately certified for each test it performs. The Current Procedural Terminology (CPT) codes that CMS considers to be laboratory tests under CLIA (and thus requiring certification) change each year. Make sure your billing staffs are aware of these changes.

Background

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.

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

- G0434QW, January 28, 2015, Healgen Amphetamine Test Cassette;
- G0434QW, January 28, 2015, Healgen Amphetamine Test Cup;
- G0434QW, January 28, 2015, Healgen Amphetamine Test Dip Card;
- G0434QW, January 28, 2015, Healgen Amphetamine Test Strip;
- G0434QW, January 28, 2015, Healgen Oxycodone Test Cassette;
- G0434QW, January 28, 2015, Healgen Oxycodone Test Cup;
- G0434QW, January 28, 2015, Healgen Oxycodone Test Dip Card;
- G0434QW, January 28, 2015, Healgen Oxycodone Test Strip;
- G0434QW, March 4, 2015, Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Cassette;
- G0434QW, March 4, 2015, Healgen Scientific LLC Healgen MDMA (Ecstasy)Test Cup;
- G0434QW March 4, 2015, Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Dip Card;
- G0434QW, March 4, 2015, Healgen Scientific LLC Healgen MDMA (Ecstasy) Test Strip;
- G0434QW, March 4, 2015, Healgen Scientific LLC Healgen Phencyclidine Test Cassette;
- G0434QW, March 4, 2015, Healgen Scientific LLC Healgen Phencyclidine Test Cup;
- G0434QW March 4, 2015, Healgen Scientific LLC Healgen Phencyclidine Test Dip Card;

- G0434QW, March 4, 2015, Healgen Scientific LLC Healgen Phencyclidine Test Strip;
- G0434QW, March 31, 2015, Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cards;
- G0434QW, March 31, 2015, Medical Distribution Group Inc., Identify Home Drug Testing Device Test Cups;
- G0434QW, April 20, 2015, Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests;
- G0434QW, April 20, 2015, Chemtron Biotech, Inc. Chemtrue Drug Screen Cup Tests with OPI 2000;
- G0434QW, April 29, 2015, Quest Products, Inc. DrugHAWK MDMA and OPI Drug Test Cup (Urine){Cup format};
- G0434QW, April 30, 2015, Quest Products, Inc. DrugHAWK Drug Test Cup;
- G0434QW, May 6, 2015, Quest Products, Inc. DrugHAWK Buprenorphine Drug Test Cup;
- 87651QW, May 15, 2015, Roche Molecular, cobas Liat System;
- 87880QW, May 26, 2015, Medline Strep A Test Strip){Throat Swabs};
- 80061QW, 82465QW, 83718QW, 84478QW, May 28, 2015, Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Lipid Panel test strips);
- 80061QW, 82465QW, 83718QW, 84478QW, May 28, 2015, Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Lipid Panel test strips);
- 82947QW, May 28, 2015, Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips);
- 82947QW, May 28, 2015, Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips;
- 82947QW, May 28, 2015, Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips);
- 82947QW, May 28, 2015, Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips);
- G0434QW, June 3, 2015, Native Diagnostics International; DrugSmart Drug Screen Cup Tests with OPI 2000;
- G0434QW, June 3, 2015, Onsite Testing Specialists, Inc. On-site Testing Specialists Drug Screen Cup Tests;

- G0434QW, June 3, 2015, Onsite Testing Specialists, Inc. On-site Testing Specialists Drug Screen Cup Tests with OPI 2000;
- G0434QW, June 4, 2015, Transmetron, Inc. Invitro Pro Drug Test Cards; and
- 87651QW, July 15, 2015, Alere i Instrument.

The new CPT code 87651QW has been assigned for the Streptococcus group A test performed on the Roche Molecular cobas Liat System and the Alere i Instrument. This test system utilizes nucleic acid amplification technology to detect Group A Streptococcus.

Please note that the CPT codes for the following tests do not require a QW modifier to be recognized as a waived test, (These CPT codes are found on page 1 of the attachment to CR9261.):

- 81002, Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen;
- 81025, Urine pregnancy tests by visual color comparison;
- 82270, Fecal occult blood;
- 82272, Fecal occult blood;
- 82962, Blood glucose by glucose monitoring devices cleared by the FDA for home use;
- 83026, Hemoglobin by copper sulfate – non-automated;
- 84830, Ovulation tests by visual color comparison for human luteinizing hormone;
- 85013, Blood count; spun microhematocrit; and
- 85651, Erythrocyte sedimentation rate – non-automated.

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

Additional Information

The official instruction, CR 9261, issued to your MAC regarding this change is available at **http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3327CP.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.