

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



In September 2012, the Centers for Medicare & Medicaid Services (CMS) announced the availability of a new electronic mailing list for those who refer Medicare beneficiaries for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Referral agents play a critical role in providing information and services to Medicare beneficiaries. To ensure you give Medicare patients the most current DMEPOS Competitive Bidding Program information, CMS strongly encourages you to review the information sent from this new electronic mailing list. In addition, please share the information you receive from the mailing list and the link to the ["mailing list for referral agents"](#) subscriber webpage with others who refer Medicare beneficiaries for DMEPOS. Thank you for signing up!

MLN Matters® Number: MM8439 **Revised**

Related Change Request (CR) #: CR 8439

Related CR Release Date: October 28, 2013

Effective Date: January 1, 2014

Related CR Transmittal #: R2804CP

Implementation Date: January 6, 2014

New Waived Tests

This article was revised on October 29, 2013, to reflect a new Change Request (CR). The CR corrects the spelling of **"Premier Integrity Solutions P/Tox Drug Screen Cup"**. The transmittal number, CR release date and web link to the transmittal was also changed. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare Claims Administration Contractors (Medicare Contractors) for services to Medicare beneficiaries.

Provider Action Needed

If you do not have a valid, current, Clinical Laboratory Improvement Amendments of 1998 (CLIA) certificate and submit a claim to your Medicare Carrier or A/B MAC for a Current Procedural Terminology (CPT) code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be impacted.

Disclaimer

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CLIA requires that for each test it performs, a laboratory facility must be appropriately certified. The 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) 8439, from which this article is taken, informs carriers and MACs about the latest new CPT codes that are subject to CLIA edits.

Make sure that your billing staffs are aware of these CLIA-related changes for 2014 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 Current Procedural Terminology (CPT) codes for the following new tests must have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the list attached to CR8439 (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, January 23, 2008, Phamatech At Home 12 Drug Test (Model 9308T);
- G0434QW, January 23, 2008, Phamatech At Home 12 Drug Test (Model 9308Z);
- 81003QW, January 29, 2013, Henry Schein Urispec Plus Urine Analyzer;
- G0434QW, February 27, 2013, CLIAwaived, Inc. Rapid Drug Test Cup;
- G0434QW, February 27, 2013, Clinical Reference Laboratory, Inc. Intelligent Transport Cup;
- G0434QW, February 27, 2013, Noble Medical Inc. Noble 1 Step Cup;
- G0434QW, February 27, 2013, Premier Integrity Solutions P/Tox Drug Screen Cup;
- G0434QW, February 27, 2013, US Diagnostics ProScreen Drugs of Abuse Cup;
- 84443QW, March 5, 2013, BTNX Rapid Response Thyroid Stimulating Hormone (TSH) Test Cassette (Whole Blood);
- 86308QW, March 11, 2013, Henry Schein OneStep Pro+ Mono {Whole Blood};
- G0434QW, May 15, 2013, UCP Biosciences, Inc. UCP Home Drug Screening Test Cups;
- G0434QW, May 17, 2013, Alere Toxicology Services, Inc. Tox Screen Drugs of Abuse Test Cup;
- G0434QW, June 24, 2013, Advin Multi-Drug Screen Test; and
- 87880QW, July 3, 2013, Henry Schein OneStep Pro+ Strep A Cassette.

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Additional Information

The official instruction, CR8439, issued to your MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2804CP.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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