

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



News Flash – Effective January 1, 2012, Diversified Service Options, Inc, a wholly-owned subsidiary of Blue Cross and Blue Shield of Florida Inc, acquired Highmark Medicare Services from its parent company, Highmark Inc. As a result, Highmark Medicare Services changed its name to Novitas Solutions, Inc. Novitas will continue to be the Medicare Administrative Contractor (MAC) for the J12 jurisdiction and will also continue as the Section 1011 Administrative Contractor. In the near future, the Highmark website will be changing to <http://www.Novitas-Solutions.com> on the Internet.

MLN Matters® Number: MM7795

Related Change Request (CR) #: CR 7795

Related CR Release Date: April 6, 2012

Effective Date: July 1, 2012

Related CR Transmittal #: R2439CP

Implementation Date: July 2, 2012

New Waived Tests

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare contractors (carriers and A/B Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

Provider Action Needed

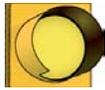


STOP – Impact to You

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.

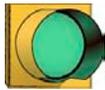
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CAUTION – What You Need to Know

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) considers to be laboratory tests under CLIA (and thus requiring certification) change each year. CR 7795, from which this article is taken, informs carriers and MACs about the latest new CPT codes that are subject to CLIA edits.



GO – What You Need to Do

Make sure that your billing staffs are aware of these CLIA-related changes for 2012 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 attached list (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.

CPT Code	Effective Date	Description
G0434QW	April 22, 2011	Diagnostic Test Group Clarity Multiple Drug Screen Cups
87804QW	December 9, 2011	BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader}
G0434QW	December 14, 2011	Alere Toxicology Services Alere iCassette DX Drug Screen
82055QW	January 6, 2012	Jant Pharmacal Corporation Accustrip Saliva Alcohol Test Strip
82055QW	January 6, 2012	Alfa Scientific Designs Inc. Oral-View Saliva Alcohol Test Strip
83861QW	January 23, 2012	TearLab Corporation TearLab Osmolarity System
G0434QW	January 26, 2012	Alere iCassette Drug Screen
87804QW	January 27, 2012	Alere Influenza A & B Test (For use with nasal Swabs only.)

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CPT Code	Effective Date	Description
87808QW	February 3, 2012	Sekisui Diagnostics, LLC OSOM Trichomonas Rapid Test
87880QW	February 3, 2012	Sekisui Diagnostics LLC, OSOM Ultra Strep A Test
87880QW	March 1, 2012	Sekisui Diagnostics LLC, OSOM Strep A Test{direct from throat swab}

The new waived CPT code, 83861QW, has been assigned for the osmolarity test performed using the TearLab Corporation TearLab Osmolarity System.

Additional Information

The official instruction, CR 7795 issued to your carrier and A/B MAC regarding this change may be viewed at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2439CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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