

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



Revised product from the Medicare Learning Network® (MLN)

- [“Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse”](#), Booklet, ICN 907798, downloadable



MLN Matters® Number: MM8560

Related Change Request (CR) #: CR 8560

Related CR Release Date: January 10, 2014

Effective Date: April 1, 2014

Related CR Transmittal #: R2854CP

Implementation Date: April 7, 2014

New Waived Tests

Provider Types Affected

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

Provider Action Needed



STOP – Impact to You

This article is based on Change Request (CR) 8560, which informs MACs of new Clinical Laboratory Improvement Act (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 so that they can accurately process claims. There are six (6) newly added waived complexity tests.

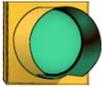
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CAUTION – What You Need to Know

(CLIA regulations require that, for each test it performs, a laboratory facility must be appropriately certified. The Current Procedural Terminology (CPT) codes that CMS considers to be laboratory tests under CLIA (and thus requiring certification) change each year. CR 8560, from which this article is taken, informs 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 2014 and that you remain current with certification requirements.

Background

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that the Medicare and Medicaid programs 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 to be recognized as a waived test. However, the tests mentioned on the first page of the list attached to CR 8560 (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:

CPT Code	Effective Date	Description
G0434QW	May 29, 2013	"SCI International Inc. New Choice At Home Drug Test: Marijuana (Strip Format)"
82465QW 83718QW 84478QW 82962	July 1, 2013	Infopia USA, LipidPro® Professional Lipid Profile and Glucose Measuring System
G0434QW	July 29, 2013	Alere iCup DX 14 (Cassette Dip Card format)
G0434QW	September 25, 2013	American Screening Corporation, Inc. Discover Drug Test Cards
G0434QW	September 25, 2013	American Screening Corporation, Inc. Discover Multi-Panel Drug Test Cups

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CPT Code	Effective Date	Description
82465QW 83718QW 84478QW 82962	November 12, 2013	Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System

Additional Information

The official instruction, CR 8560, issued to your MAC, regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2854CP.pdf> on the CMS website.

For further information, you may view the CLIA webpage available at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html> 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.

News Flash - Generally, Medicare Part B covers one flu vaccination and its administration per flu season for beneficiaries without co-pay or deductible. Now is the perfect time to vaccinate beneficiaries. Health care providers are encouraged to get a flu vaccine to help protect themselves from the flu and to keep from spreading it to their family, co-workers, and patients. Note: The flu vaccine is not a Part D-covered drug. For more information, visit:

- [MLN Matters® Article #MM8433](#), "Influenza Vaccine Payment Allowances - Annual Update for 2013-2014 Season"
- [MLN Matters® Article #SE1336](#), "2013-2014 Influenza (Flu) Resources for Health Care Professionals"
- [HealthMap Vaccine Finder](#) - a free, online service where users can search for locations offering flu and other adult vaccines. While some providers may offer flu vaccines, those that don't can help their patients locate flu vaccines within their local community.

The CDC website for [Free Resources](#), including [prescription-style tear-pads](#) that allow you to give a customized flu shot reminder to patients at high-risk for complications from the flu.

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