



News Flash – On June 9, 2009, the Centers for Medicare & Medicaid Services (CMS) conducted a national provider conference call on the HIPAA Versions 5010 and D.O. You can view the presentation, transcript and listen to the audiofile from that call by accessing http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/downloads/6-9-2009_National_Provider_Call.pdf on the CMS website.

MLN Matters® Number: MM6570

Related Change Request (CR) #: 6570

Related CR Release Date: August 21, 2009

Effective Date: October 1, 2009

Related CR Transmittal #: R1799CP

Implementation Date: October 5, 2009

Note: This article was updated on January 3, 2013, to reflect current Web addresses. All other information remains unchanged.

New Waived Tests

Provider Types Affected

Clinical laboratories and providers that submit claims to Medicare carriers or Medicare Administrative Contractors (MACs) for laboratory test services provided to Medicare beneficiaries are affected.

Provider Action Needed

This article, based on Change Request (CR) 6570, alerts clinical laboratories and providers that the Centers for Medicare & Medicaid Services (CMS) has listed the latest tests approved by the Food and Drug Administration (FDA) as waived tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The tests newly added to the waived tests are in the table in the Background section of this article. Be sure your billing staffs are aware of these changes.

Background

CLIA regulations require a facility to be appropriately certified for each test it performs. To ensure that Medicare and Medicaid only pay for laboratory tests categorized as waived

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complexity under CLIA in facilities with a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level. CMS identifies waived tests by providing an updated list of waived tests to Medicare contractors on a quarterly basis via a Recurring Update Notification. To be recognized as a waived test, some CLIA waived tests have unique Healthcare Common Procedure Coding System (HCPCS) procedure codes and some must have a QW modifier included with the HCPCS code.

Listed below are the latest tests approved by the 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 attachment to CR 6570 at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1799CP.pdf> on the CMS website (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 |
|------------------------------|---------------------|--|
| 82274QW G0328QW | December 4, 2008 | Jant Pharmacal Accutest Immunological Fecal Occult Blood Test (iFOBT) |
| 84703QW | January 26, 2009 | Siemens Clinitek Status Urine Chemistry Analyzer |
| 82962, 82465QW | January 29, 2009 | Roche Diagnostics Accutrend Plus System {fingerstick whole blood} |
| 82274QW G0328QW | March 5, 2009 | Henry Schein One Step+ iFOBT |
| 81003QW, 82044QW, 82570QW | March 5, 2009 | Siemens Clinitek Status Urine Chemistry Analyzer |
| 87804QW | March 10, 2009 | EarlyDetect Pro Influenza A Test |
| 87804QW | March 10, 2009 | EarlyDetect Pro Influenza B Test |
| 83986QW | March 16, 2009 | Lil' Drug Store Products Inc. Vagi-Screen Vaginal Health Test |
| 86308QW | April 14, 2009 | Acceava Mono II {Whole Blood} |
| 80101QW | April 30, 2009 | 1 Step Detect Associates DTX Drug Test Cup Integrated E-Z Split Key Cup II |
| 87880QW | May 21, 2009 | Inverness Medical Signify Strep A Cassette (Inverness Medical Innovations) |

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| CPT Code | Effective Date | Description |
|----------|----------------|---|
| 86318QW | May 21, 2009 | Inverness Medical Signify H. Pylori Whole Blood |
| 86318QW | May 21, 2009 | EarlyDetect H. Pylori Whole Blood Rapid Test |

In addition, the CPT code assigned to the HemoCue Albumin 201 System has been changed from 83520QW to 82043QW, with an effective date of October 1, 2009. Medicare contractors will deny the use of code 83520QW submitted by facilities with a valid, current CLIA certificate of waiver for dates of service on or after October 1, 2009.

Please note that your Medicare contractor will not search their files to either retract payment or retroactively pay claims processed before CR 6570 is implemented. However, they will adjust claims that you bring to their attention.

Additional Information

You can find the official instruction, CR 6570, issued to your carrier or MAC by visiting <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1799CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or 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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