

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



News Flash – Are you billing correctly for ordered/referred services? Will you be impacted when the Centers for Medicare & Medicaid Services (CMS) turns on the edits for these services? See the revised MLN Matters® articles [SE1221](#), [SE1011](#), and MLN fact sheets [“Medicare Enrollment Guidelines for Ordering/Referring Providers”](#) and [“The Basics of Medicare Enrollment for Physicians Who Infrequently Receive Medicare Reimbursement”](#) to learn what you need to do.

MLN Matters® Number: MM7868

Related Change Request (CR) #: CR 7868

Related CR Release Date: July 20, 2012

Effective Date: October 1, 2012

Related CR Transmittal #: R2496CP

Implementation Date: October 1, 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

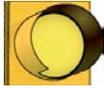


STOP – Impact to You

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.

Disclaimer

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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 7868, 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	March 14, 2012	Wondfo Oxycodone Urine Test {Dip card format}
G0434QW	March 14, 2012	Wondfo Oxycodone Urine Test {Cup format}
87880QW	March 23, 2012	McKesson Strep A Test - Dipstick
87880QW	March 23, 2012	McKesson Strep A Test - Twist
86318QW	April 3, 2012	McKesson H. pylori Test (Whole Blood)
87804QW	April 20, 2012	Sofia Analyzer and Influenza A+B FIA (for user with nasal swabs and nasopharyngeal swabs)
85610QW	May 8, 2012	AlereINRatio®2 PT/INR Home Monitoring System {Prescription Home Use}
83986QW	May 8, 2012	Dale Medical Products, Inc. RightLevel pH
83986QW	May 8, 2012	Dale Medical Products, Inc. RightSpot pH
G0434QW	May 22, 2012	Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Cassette Tests
G0434QW	May 22, 2012	Chemtron Biotech, Inc. Chemtrue Single/Multi-Panel Drug Screen Dip Card Tests

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Additional Information

The official instruction, CR 7868, issued to your carrier and A/B MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2496CP.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.hhs.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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