

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



News Flash – The Centers for Medicare & Medicaid Services (CMS) has launched the 2011 Medicare Contractor Provider Satisfaction Survey (MCPSS) and is waiting to hear from you. This survey offers Medicare Fee-For-Service (FFS) providers and suppliers an opportunity to provide feedback on interactions with their Medicare contractors. The survey will be sent to a random sample of approximately 30,000 Medicare FFS providers and suppliers. Those who are selected to participate will be notified starting in January. If selected to participate, please complete this important survey. To learn more about the MCPSS, please visit <http://www.cms.gov/MCPSS> on the CMS website.

MLN Matters® Number: MM7266 **Revised**

Related Change Request (CR) #:7266

Related CR Release Date: March 28, 2011

Effective Date: April 1, 2011

Related CR Transmittal #: R2187CP

Implementation Date: April 4, 2011

New Waived Tests

Note: This article was revised on March 29, 2011, to reflect a revised CR7266. The CR was revised to change the effective date of the G0434QW code from January 1, 2011, to April 1, 2011. In addition, the CR release date, transmittal number, and the Web address for accessing CR7266 were changed. All other information remains the same.

Provider Types Affected

This article is for clinical diagnostic laboratories billing Medicare Carriers or Part A/B Medicare Administrative Contractors (MACs) for laboratory tests.

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

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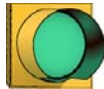
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Current Procedural Terminology (CPT) code that is considered to be a laboratory test requiring a CLIA certificate, your Medicare payment may be impacted.



CAUTION – What You Need to Know

For dates of service on or after April 1, 2011, claims that use code G0431QW will be denied. Effective January 1, 2011, the code G0430 has been deleted and replaced with code G0434. Therefore, the code G0434QW replaces G0430QW in the list attached to CR7266.



GO – What You Need to Do

Make sure that your billing staffs are aware of these CLIA-related changes for 2011 and that you remain current with certification requirements.

Background

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, therefore, requiring certification) change each year. CR7266, from which this article is taken, informs carriers and MACs about the latest new CPT codes that are subject to CLIA edits

Listed below are the latest tests approved by the Food and Drug Administration as waived tests under CLIA. The tests are valid as soon as they are approved. The CPT codes for the following new tests **MUST have the modifier QW** to be recognized as a waived test. Note, however, that the tests mentioned on the first page of the list attached to CR7266 (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
87880QW	October 4, 2010	BTNX, Inc. Strep A Rapid Test
86308QW	October 4, 2010	Consult Diagnostics Mononucleosis Cassette {Whole Blood}
82274QW G0328QW	October 4, 2010	BTNX Inc. Rapid Response Fecal Immunochemical Test (FIT)
82274QW G0328QW	October 4, 2010	American IVD Biotechnology Services Inc. FOB/CRC Advanced+

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CPT Code	Effective Date	Description
G0434QW	April 1, 2011	Amedica Biotech AmediCheck Instant Test Cup
G0434QW	April 1, 2011	Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	Insight Medical Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	Jant Pharmacal Corporation Accutest Drug Test Cup
G0434QW	April 1, 2011	Micro Distributing II, Ltd Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	Millenium Laboratories Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	NexScreen LLC, NexScreen Cup
G0434QW	April 1, 2011	On the Spot Drug Testing Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	Physicians' Test Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	Total Diagnostic Solutions Multi-Drug of Abuse Urine Test
G0434QW	April 1, 2011	UCP Biosciences, Inc. Drug Screening Test Cards
G0434QW	April 1, 2011	UCP Biosciences, Inc. Multiple Drug Screen Cups

In 2011, the code G0430 has been deleted and replaced by G0434. Also, in 2011, the description for code G0431 was changed from "Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class" to "Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter."

Therefore, the following CLIA waived complexity test systems mentioned in the attachment to CR7266 had their code changed from G0431QW to G0434QW;

- Phamatech QuickScreen One Step Amphetamine Test,
- Accu-Stat Drugs of Abuse Home Test for Marijuana (THC),
- ADC CLIA Waived Marijuana (THC) Test,
- First Check Diagnostics LLC, First Check Home Drug Test Marijuana,
- Phamatech QuickScreen One Step THC Screening Test,
- Phamatech At Home Drug Test (Model 9078),
- Phamatech At Home Drug Test (Model 9078T),
- Worldwide Medical Corporation, First Check® Home Drug Test (THC),
- Phamatech At Home Drug Test (Model 9073),
- Phamatech At Home Drug Test (Model 9073T),

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- Phamatech QuickScreen One Step Cocaine Screening Test,
- Phamatech At Home Drug Test (Model 9068),
- Phamatech QuickScreen One Step Methamphetamine Test,
- DyanGen NicCheck II Test Strips,
- Mossman Associates, Inc. NicCheck I Test Strips,
- Phamatech At Home Drug Test (Model 9083),
- Phamatech QuickScreen One Step Opiate Screening Test, and
- Phamatech At Home Drug Test (Model 9133).

Note that Medicare contractors will not search their files to either retract payment or retroactively pay claims. They will, however, adjust claims if they are brought to their attention.

Additional Information

The official instruction, CR7266 issued to your carrier, A/B MAC, regarding this change may be viewed at <http://www.cms.gov/Transmittals/downloads/R2187CP.pdf> on the CMS website. The list of tests granted waived status under CLIA is attached to the CR.

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.

News Flash - It's Not too Late to Give and Get the Flu Vaccine. Take advantage of each office visit and continue to protect your patients against the seasonal flu. Medicare will continue to pay for the seasonal flu vaccine and its administration for all Medicare beneficiaries through the entire flu season. The Centers for Disease Control and Prevention (CDC) recommends that patients, health care workers and caregivers be vaccinated against the seasonal flu. Protect your patients. **Protect your family. Protect yourself. Get Your Flu Vaccine - Not the Flu.**

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