



News Flash – Did you know? Medicare’s Internet-based PECOS creates a custom application tailored to your enrollment scenario. Learn more at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html> on the CMS website.

MLN Matters® Number: MM7084

Related Change Request (CR) #: 7084

Related CR Release Date: August 27, 2010

Effective Date: October 1, 2010

Related CR Transmittal #: R2038CP

Implementation Date: October 4, 2010

Note: This article was updated on December 10, 2012, to reflect current Web addresses. All other information remains unchanged.

New Waived Tests

Provider Types Affected

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

Provider Action Needed

This article is based on Change Request (CR) 7084, which informs Medicare contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration (FDA). Be sure your billing staffs are aware of the changes.

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 Current Procedural Terminology (CPT) codes for the following new tests must

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have the modifier QW, defined as CLIA waived test, to be recognized as a waived test. However, the test with CPT code 82962 does not require a QW modifier to be recognized as a waived test.

CPT Code	Effective Date	Description
G0430QW	January 1, 2010	Noble medical Inc. Split-Specimen Cup
82274QW, G0328QW	March 1, 2010	Inverness Medical Clearview iFOBT Complete Fecal Occult Blood Test
82010QW, 82962 (no QW modifier needed)	March 2, 2010	Nova Biomedical Nova Max Plus Glucose and B-Ketone Monitoring System
83986QW	April 15, 2010	Common Sense Ltd. VS-Sense Test{qualitative}
85610QW	April 15, 2010	CoaguSense Self-Test Prothrombin Time/INR Monitoring System (Prescription Home Use)
G0430QW	April 21, 2010	Redwood Toxicology Laboratory, Inc Reditest Freedom Cup
G0430QW	April 21, 2010	Noble Medical Inc. NOBLE 1 Step Cup {OTC}
G0430QW	April 30, 2010	Express Diagnostics, DrugCheck Waive Cup
G0430QW	April 30, 2010	Express Diagnostics International Inc. DrugCheck Waive Multiple Drug Screen Cups
81003QW	June 3, 2010	Cole-Talyor Marketing Inc. CTI-120 Urine Strip Analyzer

Note that Medicare contractors will not search their files to either retract payment for claims already paid or to retroactively pay claims processed prior to implementation of these changes. However, they will adjust such claims that you bring to their attention.

Additional Information

If you have questions, please contact your Medicare carrier and/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 Centers for Medicare & Medicaid Services (CMS) website.

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The official instruction, CR 7084, issued to your Medicare carrier and/or MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2038CP.pdf> on the CMS website.

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