DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

MLN Matters® Number: MM9956 | **Related Change Request (CR) #: CR 9956**

Related CR Release Date: January 20, 2017 | **Effective Date: April 1, 2017**

Related CR Transmittal #: R3696CP | **Implementation Date: April 3, 2017**

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 provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9956 informs MACs of new Clinical Laboratory Improvement Amendments of 1988 (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 MACs of the new tests so that they can accurately process claims. Make sure that your billing staffs are aware of these CLIA-related changes.

Background

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests categorized as waived complexity under CLIA in facilities with 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 have the modifier QW to be recognized as a waived test. However, the tests mentioned on the first page of the list attached to CR9956 (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:

- G0477QW [from July 7, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], July 7, 2016, TransMed Company, CLIA Screen In-Vitro Multi-Drug Urine Test Dip Card
- G0477QW [from July 7, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], July 7, 2016, TransMed Company, CLIA Screen In-Vitro Multi-Drug Urine Test Dip Cup
- 82274QW, G0328QW, July 27, 2016, Pinnacle BioLabs Second Generation FIT Fecal Occult Blood (FOB) Self-Test {Cassette}
- G0477QW [from August 11, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], August 11, 2016, Nobel Medical Inc., AEON Multi-Drug Urine Test Cup
- G0477QW [from August 11, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], Nobel Medical Inc., August 11, 2016, AEON Multi-Drug Urine Test Dip Card
- G0477QW [from August 11, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], August 11, 2016, Nobel Medical Inc., INSTA-SCREEN Multi-Drug Urine Test Dip Card
- 82274QW, G0328QW, September 6, 2016, ProAdvantage Immunochemical Fecal Occult Blood Test
- 87880QW, September 16, 2016, Cardinal Health Strep A Cassette Rapid Test
- G0477QW [from September 16, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], September 16, 2016, Premier Biotech, Inc., MDETOX Multi-Drug Urine Test Cup
- G0477QW [from September 16, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], September 16, 2016, Premier Biotech, Inc., MDETOX Multi-Drug Urine Test Dip Card

- 81003QW, October 7, 2016. Moore Medical LLC mooremedical U120 Urine Analyzer
- 87633QW, October 7, 2016, BioFire Diagnostics, FilmArray 2.0 EZ Configuration Instrument (Viral and Bacterial Nucleic Acids) {Nasopharyngeal Swabs}
- 87804QW, October 7, 2016, BioSign Flu A+B {Nasal and nasopharyngeal swabs}
- G0477QW [from October 24, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], October 24, 2016, Identify BioSciences Inc., Identifi Multi-Panel Drug Test Cups (Urine) {Cup Format}
- G0477QW [from October 25, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], October 25, 2016, UCP Biosciences, Inc. U-Card Drug Test Screen (Urine) {Card Format}
- G0477QW [from October 25, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], October 25, 2016, UCP Biosciences, Inc. U-Cup Drug Test Screen (Urine) {Cup Format}
- G0477QW [from October 26, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], Intrinsic Interventions Inc., Vista Flow
- 87804QW, November 15, 2016, LifeSign LLC, Status Flu A+B
- 87804QW, November 21, 2016, Sekisui Diagnostics LLC, OSOM Ultra Flu A&B Test
- G0477QW [from November 23, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], November 23, 2016, Medical Distribution Group Inc., Identify Diagnostics Drug Test Cards (UPC Biosciences, Inc.)
- G0477QW [from November 23, 2016, to December 31, 2016], 80305QW [on and after January 1, 2017], November 23, 2016, Medical Distribution Group Inc., Identify Diagnostics Drug Test Cups (UPC Biosciences, Inc.)
- 87804QW, November 25, 2016, OraSure QuickFlu Rapid A+B Test {Nasal and Nasopharyngeal Swabs

The HCPCS code G0477 [Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg, immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service] was discontinued on 12/31/2016. The new HCPCS code 80305 [Drug test(s), presumptive, any number of drug classes, any number of devices or procedures (eg, immunoassay); capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges) includes sample validation when performed, per date of service] was effective 1/1/2017. HCPCS code 80305QW describes the waived testing previously assigned the code G0477QW. All tests in the attachment that previously had HCPCS G0477QW are now assigned 80305QW.

The new waived complexity code 87633QW [Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets] was assigned for the testing performed by BioFire Diagnostics, FilmArray 2.0 EZ Configuration Instrument (Viral and Bacterial Nucleic Acids){Nasopharyngeal Swabs}.

The attachment to CR9956 has been re-organized. HCPCS codes with more than 20 test systems listed in previous transmittal attachments will now not mention the specific waived complexity test system. Instead, there will be a generic test system name and a statement to refer to the FDA waived analytes internet site (**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm**) for the specific test system name. The HCPCS codes mentioned on the attachment that will now only be mentioned in a generic manner are G0477QW (80305QW effective 1/1/2017), 81003QW, 82274QW, G0328QW, 86308QW, 86318QW, and 87880QW. For these codes, future New Waived Test transmittals will only mention the specific name of the latest FDA test system in the transmittal and not be included in the attachment.

MACs will not search their files to either retract payment or retroactively pay claims based on these changes. However, MACs should adjust claims that you bring to their attention.

Additional Information

The official instruction, CR9956, issued to your MAC regarding this change is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3696CP.pdf**.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/**.