| CMS Manual System | Department of Health & Human Services (DHHS) |
|---|---|
| Pub 100-04 Medicare Claims Processing | Centers for Medicare & Medicaid Services (CMS) |
| **Transmittal 10831** | **Date: June 2, 2021** |
| | **Change Request 12131** |

**Transmittal 10613, dated March 10, 2021, is being rescinded and replaced by Transmittal 10831, dated, June 2, 2021, to revise sections of the background related to the QW modifier and to revise business requirement 12131.2, which is also related to the QW modifier. All other information remains the same.**

**SUBJECT: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits**

**I. SUMMARY OF CHANGES:** This Change Request (CR) informs contractors about the new HCPCS codes for 2021 that are subject to and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, section 70.9.

**EFFECTIVE DATE: April 1, 2021**
*Unless otherwise specified, the effective date is the date of service.*
**IMPLEMENTATION DATE: April 5, 2021**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| N/A | N/A |

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Recurring Update Notification**

# Attachment - Recurring Update Notification

| Pub. 100-04 | Transmittal: 10831 | Date: June 2, 2021 | Change Request: 12131 |
| --- | --- | --- | --- |

Transmittal 10613, dated March 10, 2021, is being rescinded and replaced by Transmittal 10831, dated, June 2, 2021, to revise sections of the background related to the QW modifier and to revise business requirement 12131.2, which is also related to the QW modifier. All other information remains the same.

SUBJECT: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

EFFECTIVE DATE: April 1, 2021
*Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 5, 2021

## I.    GENERAL INFORMATION

A.    Background:   The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The HCPCS codes that are considered a laboratory test under CLIA change each year. Contractors need to be informed about the new HCPCS codes that are both subject to CLIA edits and excluded from CLIA edits.

The following HCPCS code was discontinued on March 31, 2020:

- 0006U - Testing for presence of interacting medications, substances, supplements and foods in urine.

The following HCPCS codes were discontinued on June 30, 2020:

- 0124U - Analysis of 3 substances in maternal blood to assess risk of abnormal chromosomes in fetus;
- 0125U – Analysis of 5 substances in maternal blood to assess risk of abnormal chromosomes in fetus and preeclampsia; and
- 0127U – Analysis of 3 substances in maternal blood to assess risk of preeclampsia.

The following HCPCS code was discontinued on October 5, 2020:

- 87450 - Immunologic analysis for detection of organism by immunoassay technique, single step method.

The following HCPCS codes were discontinued on December 31, 2020:

- 81545- Gene analysis (thyroid cancer); and
- 0111T - Measurement of long-chain omega fatty acids in red blood cell (RBC) membranes.

The HCPCS codes that follow are all subject to CLIA edits. These lists do not include new HCPCS codes for waived tests or provider-performed microscopy procedures. All these HCPCS codes require a facility to

have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests, unless a facility with a current CLIA certificate of waiver (certificate type code 2) or CLIA certificate for provider-performed microscopy procedures (certificate type code 4) bills the appropriate HCPCS code with a QW modifier.

1. The HCPCS codes listed below were added on February 4, 2020 and are subject to CLIA edits.

- U0001 - Cdc 2019 novel coronavirus (2019-ncov) real-time rt-pcr diagnostic panel; and
- U0002 - 2019-ncov coronavirus, sars-cov-2/2019-ncov (covid-19), any technique, multiple types or subtypes (includes all targets), non-cdc.

2. The HCPCS code listed below was added on March 13, 2020 and is subject to CLIA edits.

- 87635 - Amplifed DNA or RNA probe detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antigen.

3. The HCPCS codes listed below were added on April 1, 2020 and are subject to CLIA edits.

- 0014M – Liver disease, analysis of 3 biomarkers (hyaluronic acid [ha], procollagen iii amino terminal peptide [piiinp], tissue inhibitor of metalloproteinase 1 [timp-1]), using immunoassays, utilizing serum, prognostic algorithm reported as a risk score and risk of liver fibrosis and liver-related clinical events within 5 years;
- 0163U - Screening test for 3 protein biomarkers of colorectal cancer in serum or plasma specimen;
- 0164U - Test for detection of antibodies associated with irritable bowel syndrome in plasma specimen, reported as elevated or not elevated;
- 0165U - Test for detection of antigens associated with peanut allergy in blood specimen, reported as probability of peanut allergy;
- 0166U - Liver disease test panel in serum specimen;
- 0167U – Test for detection of human chorionic gonadotropin (pregnancy hormone) in blood specimen;
- 0168U – DNA analysis for detection of abnormal chromosome number of fetus in maternal plasma specimen;
- 0169U – Gene analysis (nudix hydrolase 15) and TPMT (thiopurine S-methyltransferase) for detection of common variants;
- 0170U – RNA gene sequencing for probability of autism spectrum disorder in saliva specimen; and
- 0171U - DNA analysis of targeted sequences in 23 genes for detection of abnormalites associated with myeloid leukemia, myelodysplastic syndrome, and myeloproliferative cancer.

4. The HCPCS codes listed below were added on April 10, 2020 and are subject to CLIA edits.

- 86328 - Test for detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody, qualitative or semiquantitative; and
- 86769 - Measure of severe acute respiratory syndrome coronavirus 2 (Covid-19) antibody.

5. The HCPCS codes listed below were added on April 14, 2020 and are subject to CLIA edits.

- U0003 - Infectious agent detection by nucleic acid (dna or rna); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), amplified probe technique, making use of high throughput technologies as described bycms-2020-01-r; and
- U0004 - 2019-ncov coronavirus, sars-cov-2/2019-ncov (covid-19), any technique, multiple types or subtypes (includes all targets), non-cdc, making use of high throughput technologies as described by cms-2020-01-r

6. The HCPCS code listed below was added on May 20, 2020 and is subject to CLIA edits.

- 0202U - Test for detection of respiratory disease-causing organisms from back of nose and throat (nasopharynx) specimen, 22 target organisms including severe acute respiratory syndrome coronavirus 2.

7. The HCPCS codes listed below were added on June 25, 2020 and are subject to CLIA edits.

- 0223U - Test for detection of respiratory disease-causing organisms from back of nose and throat (nasopharynx) specimen, 22 target organisms including severe acute respiratory syndrome coronavirus 2;
- 0224U - Measurement of antibody to severe acute respiratory syndrome coronavirus 2 (COVID-19); and
- 87426 - ELISA detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) antigen.

8. The HCPCS codes listed below were added on July 1, 2020 and are subject to CLIA edits.

- 0172U – DNA gene analysis (BRCA1, DNA repair associated and BRCA2, DNA repair associated) for detection of mutations associated with breast cancer;
- 0173U – Gene analysis panel for detection of variants in 14 genes associated with psychiatric disorders;
- 0174U – Mass spectrometry testing for 30 protein targets in tissue specimen to predict benefit of cancer therapy agents;
- 0175U - Gene analysis panel for detection of variants in 15 genes associated with psychiatric disorders;
- 0176U - Test for detection of IgG antibodies associated with irritable bowel syndrome;
- 0177U - DNA gene analysis (phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha) for detection of mutations associated with breast cancer;
- 0178U - Test for detection of antigens associated with peanut allergy in blood specimen, reported as minimum exposure for clinical reaction;
- 0179U - Cell-free DNA analysis of targeted sequences in 23 genes for detection of mutations associated with non-small cell lung cancer;
- 0180U - Red blood cell antigen genotyping, ABO blood group;
- 0181U - Red blood cell antigen genotyping, Colton blood group;
- 0182U - Red blood cell antigen genotyping, CD55 molecule [Cromer blood group] exons 1-10;
- 0183U - Red blood cell antigen genotyping, solute carrier family 4 member 1 [Diego blood group] exon 19;
- 0184U - Red blood cell antigen genotyping, ADP-ribosyltransferase 4 [Dombrock blood group] exon 2;
- 0185U - Red blood cell antigen genotyping, fucosyltransferase 1 [H blood group] exon 4;
- 0186U - Red blood cell antigen genotyping, fucosyltransferase 2 [H blood group] exon 2
- 0187U - Red blood cell antigen genotyping, atypical chemokine receptor 1 [Duffy blood group] exons 1-2;
- 0188U - Red blood cell antigen genotyping, glycophorin C [Gerbich blood group] exons 1-4;
- 0189U - Red blood cell antigen genotyping, glycophorin A [MNS blood group] introns 1, 5, exon 2;

- 0190U - Red blood cell antigen genotyping, glycophorin B [MNS blood group] introns 1, 5, pseudoexon 3;
- 0191U - Red blood cell antigen genotyping, CD44 molecule [Indian blood group] exons 2, 3, 6;
- 0192U - Red blood cell antigen genotyping, solute carrier family 14 member 1 [Kidd blood group] gene promoter, exon 9solute carrier family 14 member 1 [Kidd blood group] gene promoter, exon 9;
- 0193U - Red blood cell antigen genotyping, ATP binding cassette subfamily G member 2 [Junior blood group] exons 2-26;
- 0194U - Red blood cell antigen genotyping, Kell metallo-endopeptidase [Kell blood group] exon 8;
- 0195U - Gene analysis (Kruppel-like factor 1) targeted sequence analysis;
- 0196U - Red blood cell antigen genotyping, basal cell adhesion molecule [Lutheran blood group] exon 3;
- 0197U - Red blood cell antigen genotyping, intercellular adhesion molecule 4 [Landsteiner-Wiener blood group];
- 0198U - Red blood cell antigen genotyping, Rh blood group D antigen exons 1-10 and Rh blood group CcEe antigens exon 5;
- 0199U - Red blood cell antigen genotyping, erythroblast membrane associated protein [Scianna blood group] exons 4, 12;
- 0200U - Red blood cell antigen genotyping, X-linked Kx blood group exons 1-3; and
- 0201U - Red blood cell antigen genotyping, acetylcholinesterase [Cartwright blood group] exon 2.

9. The HCPCS codes listed below were added on August 10, 2020 and are subject to CLIA edits.

- 0225U - Test for detection of respiratory disease-causing organisms, 21 target organisms including severe acute respiratory syndrome coronavirus 2 (COVID-19);
- 0226U - Surrogate viral neutralization test (sVNT) for detection of antibodies to severe acute respiratory syndrome coronavirus 2 (Covid-19);
- 86408 - Screening test for detection of severe acute respiratory syndrome coronavirus 2 (Covid-19) neutralizing antibody; and
- 86409 - Measurement of neutralizing antibody to severe acute respiratory syndrome coronavirus 2 (COVID-19).

10. The HCPCS code listed below was added on September 8, 2020 and is subject to CLIA edits.

- 86413 - Severe acute respiratory syndrome coronavirus 2 (sarscov-2) (coronavirus disease [covid-19]) antibody, quantitative.

11. The HCPCS codes listed below were added on October 1, 2020 and are subject to CLIA edits.

- 0015M - Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy;
- 0016M - Oncology (bladder), mrna, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like);
- 0203U - mRNA gene expression profiling of 17 genes in whole blood specimen for evaluation of inflammatory bowel disease;
- 0204U - mRNA gene analysis of 539 genes in fine needle aspiration thyroid specimen, reported as detected or not detected;
- 0205U - Gene analysis for detection of variants in 3 genes in cheek swab specimen for neovascular age-related macular-degeneration risk associated with zinc supplements;
- 0206U - Cell aggregation testing of cultured skin cells for Alzheimer disease, reported as positive or negative for Alzheimer disease;

- 0207U - Immunofluorescence testing of cultured skin cells for Alzheimer disease, reported as probability index for Alzheimer disease;
- 0208U - mRNA gene analysis of 108 genes in fine needle aspiration thyroid specimen, reported as positive or negative for medullary thyroid carcinoma;
- 0209U - Cytogenomic analysis of whole genome for abnormal chromosomes;
- 0210U - Measurement of nontreponemal antibodies associated with syphilis;
- 0211U - Next-generation sequencing of DNA and RNA in tumor tissue specimen with interpretative report;
- 0212U - Rare diseases genetic testing of complete DNA of first affected person in family;
- 0213U - Rare diseases genetic testing of complete DNA of relative of affected person in family;
- 0214U - Rare diseases genetic testing of protein coding genes of first affected person in family;
- 0215U - Rare diseases genetic testing of protein coding genes of relative of affected person in family;
- 0216U - DNA analysis of gene sequence of 12 genes for identification and characterization of abnormalites associated with inherited disorders of movement (ataxia);
- 0217U - DNA analysis of gene sequence of 51 genes for identification and characterization of abnormalites associated with inherited disorders of movement (ataxia);
- 0218U - DNA analysis of gene sequence for identification and characterization of abnormalites associated with muscular dystrophy;
- 0219U - Gene analysis of human immunodeficiency virus targeted sequence analysis for resistance to antiviral drugs;
- 0220U - Image analysis of breast cancer cell specimen with artificial intelligence assessment;
- 0221U - Red blood cell antigen genotyping, ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase gene next generation sequencing; and
- 0222U - Red blood cell antigen genotyping, RH proximal promoter, exons 1-10, portions of introns 2-3.

12. The HCPCS codes listed below were added on October 6, 2020 and are subject to CLIA edits.

- 0240U - Infectious disease (viral respiratory tract infection), pathogen-specific rna, 3 targets (severe acute respiratory syndrome coronavirus 2 [sars-cov-2], influenza a, influenza b), upper respiratory specimen, each pathogen reported as detected or not detected; and
- 0241U - Infectious disease (viral respiratory tract infection), pathogen-specific rna, 4 targets (severe acute respiratory syndrome coronavirus 2 [sars-cov-2], influenza a, influenza b, respiratory syncytial virus [rsv]), upper respiratory specimen, each pathogen reported as detected or not detected;
- 87636 - Infectious agent detection by nucleic acid (dna or rna); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]) and influenza virus types a and b, multiplex amplified probe technique;
- 87637 - Infectious agent detection by nucleic acid (dna or rna); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), influenza virus types a and b, and respiratory syncytial virus, multiplex amplified probe technique; and
- 87811 - Infectious agent antigen detection by immunoassay with direct optical (ie, visual) observation; severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]).

13. The HCPCS code listed below was added on November 10, 2020 and is subject to CLIA edits.

- 87428 - Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [eia], enzyme-linked immunosorbent assay [elisa], fluorescence immunoassay [fia], immunochemiluminometric assay [imca]) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus (eg, sars-cov, sars-cov-2 [covid-19]) and influenza virus types a and b.

14. The HCPCS codes listed below were added on January 1, 2021 and are subject to CLIA edits.

- U0005 - Infectious agent detection by nucleic acid (dna or rna); severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), amplified probe technique, cdc or non-cdc, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (list separately in addition to either hcpcs code u0003 or u0004) as described by cms-2020-01-r2;
- 0227U - Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, includes sample validation;
- 0228U - Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer;
- 0229U - Bcat1 (branched chain amino acid transaminase 1) or ikzf1 (ikaros family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis;
- 0230U - Ar (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, x chromosome inactivation), full sequence analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (str) expansions, mobile element insertions, and variants in non-uniquely mappable regions;
- 0231U - Cacna1a (calcium voltage-gated channel subunit alpha 1a) (eg, spinocerebellar ataxia), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (str) gene expansions, mobile element insertions, and variants in non-uniquely mappable regions;
- 0232U - Cstb (cystatin b) (eg, progressive myoclonic epilepsy type 1a, unverricht-lundborg disease), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (str) expansions, mobile element insertions, and variants in non-uniquely mappable regions;
- 0233U - Fxn (frataxin) (eg, friedreich ataxia), gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, short tandem repeat (str) expansions, mobile element insertions, and variants in non-uniquely mappable regions;
- 0234U - Mecp2 (methyl cpg binding protein 2) (eg, rett syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions;
- 0235U - Pten (phosphatase and tensin homolog) (eg, cowden syndrome, pten hamartoma tumor syndrome), full gene analysis, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions;
- 0236U - Smn1 (survival of motor neuron 1, telomeric) and smn2 (survival of motor neuron 2, centromeric) (eg, spinal muscular atrophy) full gene analysis, including small sequence changes in exonic and intronic regions, duplications and deletions, and mobile element insertions;
- 0237U - Cardiac ion channelopathies (eg, brugada syndrome, long qt syndrome, short qt syndrome, catecholaminergic polymorphic ventricular tachycardia), genomic sequence analysis panel including ank2, casq2, cav3, kcne1, kcne2, kcnh2, kcnj2, kcnq1, ryr2, and scn5a, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions;
- 0238U - Oncology (lynch syndrome), genomic dna sequence analysis of mlh1, msh2, msh6, pms2, and epcam, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions;
- 0239U - Targeted genomic sequence analysis panel, solid org.an neoplasm, cell-free dna, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations;
- 80143 - Measurement of acetaminophen;
- 80151 - Measurement of amiodarone;
- 80161 - Measurement of carbamazepine-10,11-epoxide;
- 80167 - Measurement of felbamate;
- 80179 - Measurement of salicylate;

- 80181 - Measurement of flecainide;
- 80189 - Measurement of itraconazole;
- 80193 - Measurement of leflunomide;
- 80204 - Measurement of methotrexate;
- 80210 - Measurement of rufinamide;
- 81168 - Gene analysis (CCND1/IGH (t(11;14))) translocation analysis;
- 81191 - Gene analysis (neurotrophic receptor tyrosine kinase 1) translocation analysis;
- 81192 - Gene analysis (neurotrophic receptor tyrosine kinase 2) translocation analysis;
- 81193 - Gene analysis (neurotrophic receptor tyrosine kinase 3) translocation analysis;
- 81194 - Gene analysis (neurotrophic receptor tyrosine kinase 1, 2, and 3) translocation analysis;
- 81278 - Gene analysis (IGH@/BCL2 (t(14;18)) translocation analysis;
- 81279 - Gene analysis (Janus kinase 2) targeted sequence analysis;
- 81338 - Gene analysis (MPL proto-oncogene, thrombopoietin receptor) for detection of common variants;
- 81339 - Gene analysis (MPL proto-oncogene, thrombopoietin receptor) sequence analysis of exon 10;
- 81347 - Gene analysis (splicing ;factor [3b] subunit B1) for detection of common variants;
- 81348 - Gene analysis (serine and arginine-rich splicing factor 2) for detection of common variants;
- 81351 - Gene analysis (tumor protein 53) full sequence analysis;
- 81352 - Gene analysis (tumor protein 53) targeted sequence analysis;
- 81353 - Gene analysis (tumor protein 53) targeted sequence analysis for detection of known familial variant;
- 81357 - Gene analysis (U2 small nuclear RNA auxiliary factor 1) for detection of common variant;
- 81360 - Gene analysis (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) for detection of common variant - s;
- 81419 - Gene analysis panel for evaluation of genes associated with epilepsy;
- 81513 - Measurement of RNA of bacteria in vaginal fluid specimen;
- 81514 - Measurement of DNA of bacteria in vaginal fluid specimen;
- 81529 - mRNA gene analysis of 13 genes in skin melanoma tissue specimen;
- 81546 - mRNA gene analysis of 10,196 genes in fine needle aspiration thyroid specimen, reported as category result (e.g. benign, suspicious);
- 81554 - mRNA gene analysis of 190 genes associated with lung disease (idiopathic pulmonary fibrosis) in transbronchial biopsy specimen of lung;
- 82077 - Measurement of alcohol level in specimen other than breath or urine; and
- 82681 - Direct measurement of free estradiol (hormone).

"***NOTE*** This instruction is NOT intended to rescind/replace any previous instructions indicating that a laboratory with a valid CLIA certificate of waiver or CLIA certificate for provider-performed microscopy procedures be allowed to bill the above codes with a QW modifier

This Recurring Update Notification applies to Chapter 16, Section 70.9.

**B.    Policy:**   The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

## II.    BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

| Number | Requirement | Responsibility | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | Shared-System Maintainers | | | | Other | |
| | | A | B | HHH | | FISS | MCS | VMS | CWF | | |
| 12131.1 | Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits. | | X | | | | | | X | | |
| 12131.2 | Contractors shall deny payment for a claim submitted with the HCPCS codes mentioned above as subject to CLIA edits to a provider without valid current CLIA certificate, with a CLIA certificate of waiver (certificate type code 2) (when billed _**without**_ the 'QW' modifier), or with a CLIA certificate for provider-performed microscopy procedures (certificate type code 4)(when billed _**without**_ the 'QW' modifier). | | X | | | | | | | | |
| 12131.3 | Contractors shall return a claim as unprocessable if a CLIA number is not submitted on claims by providers for the HCPCS mentioned above as subject to CLIA edits. | | X | | | | | | | | |
| 12131.4 | Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention. | | X | | | | | | | | |

## III.    PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---|---|---|---|---|---|---|
| | | A/B MAC | | | DME MAC | CEDI |
| | | A | B | HHH | | |
| 12131.5 | MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly.  Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter. | | X | | | |

## IV.   SUPPORTING INFORMATION

**Section A:  Recommendations and supporting information associated with listed requirements:** N/A

*"Should" denotes a recommendation.*

| X-Ref Requirement Number | Recommendations or other supporting information: |
|---|---|
| | |

**Section B:  All other recommendations and supporting information:** N/A

## V. CONTACTS

**Pre-Implementation Contact(s):** Kathleen Todd, 410-786-3385 or kathleen.todd@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

## VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**