



## Physician Services Version

### KEY CONCEPTS OUTLINE

#### Module 9: Let us Not Forget About Diagnostic Testing: Clinical Lab, Radiology, and Other Diagnostic Services

##### I. Medicare Coverage of Diagnostic Testing

###### A. In General

1. Medicare covers diagnostic x-rays, diagnostic laboratory tests, and "other diagnostic tests." <42CFR § 410.10(e)>
2. Medicare coverage of diagnostic testing is separate from the Medicare "incident to" benefit. This means that diagnostic tests do not have to meet the "incident to" criteria in order to be covered by Medicare. They do, however, have to be performed under a specific level of physician supervision, which will be described later in this module. <Medicare Benefits Policy Manual, Chapter 15 § 80>
3. Diagnostic tests are not included in the global surgery package and therefore may be covered separately. <Medicare Claims Processing Manual, Chapter 12 §40.1. (B)>

###### B. The Professional and Technical Components

###### 1. In General

- a. Many, but not all, diagnostic tests include both a "technical component" (i.e., the technical performance of the test) and a "professional component" (i.e., physician/practitioner interpretation and written review of the test results).
  - (i) CMS sometimes uses the term "facility component" to refer to the technical component. However, in some cases, the terms have slightly different meanings.

###### 2. Determining if Separate Professional and Technical Components Are Billable

###### a. The "Modifier" Indicator

- (i) The Relative Value File contains a "modifier" indicator that, for diagnostic tests, defines whether CMS treats the test as divisible into separate professional and technical components. < See *Medicare Claims Processing Manual*, Chapter 23 Addendum, MPFSDB Record Layout>
  - (a) For diagnostic tests, the modifier indicator will have one of the following values:
    - (1) Nothing – a blank indicates a global service.
    - (2) "-26" – indicates that the professional component of the test may be billed separately, or
    - (3) "-TC" – indicates that the technical component of the test may be billed separately. <Medicare Claims Processing Manual, Chapter 23 Addendum, MPFSDB Record Layout>
  - (b) For those HCPCS codes where the modifier indicator is -26 or -TC, the Relative Value File provides separate relative values and payment policy indicators for the global test (i.e., the combined professional and technical), the professional component only, and the technical component only.
- b. PC/TC Indicator
  - (i) The Relative Value File contains a "PC/TC" indicator that also defines whether CMS treats the test as divisible into separate professional and technical components. In order to bill properly for a diagnostic test, both the "modifier" indicator and the "PC/TC" indicator for the test should be reviewed.
    - (a) The PC/TC indicator will have one of the following values: <Medicare Claims Processing Manual, Chapter 23 Addendum, MPFSDB Record Layout>
      - (1) "1" – identifies the code as a diagnostic test that is divisible into separate professional and technical components using the 26/TC modifiers.
      - (2) "2" – identifies the code as representing the professional component of a service that has separate HCPCS codes for the professional and technical components. Consequently, the 26/TC modifiers are not applicable to the code.

- a. Example – CPT code 93010 (EKG, interpretation, and report only)
- (3) “3” – identifies the code as representing the technical component of a service that has separate HCPCS codes for the professional and technical components or as a code that represents a technical component only services. Consequently, the 26/TC modifiers are not applicable to the code.
- a. Example – CPT code 93005 (EKG, tracing only, without interpretation and report)
- (4) “4” – identifies the code as a global code for which there are also separate codes for the professional and technical components. Consequently, the 26/TC modifiers are not applicable to the code.
- a. Example – CPT code 93000 (EKG, complete)
- (5) “5” – identifies the code as representing a service that is covered as “incident to.” The 26/TC modifiers are not applicable to the code.
- a. CMS has provided little guidance on the meaning of a PC/TC indicator of “5.” Although not clear, it may be that a PC/TC indicator of “5” simply means that the service is not covered when furnished in a hospital setting (since there is no “incident to” coverage for fee schedule services furnished in a hospital setting). Alternatively, a PC/TC indicator of “5” may be intended to indicate a code that is not covered under Medicare diagnostic testing benefit.
- (6) “6” – indicates that the code represents the professional interpretation of a clinical laboratory test. The 26 modifier is applicable to the code. However, TC modifier is not applicable to the code because the technical component would be paid under the Clinical Diagnostic Lab Fee Schedule, rather than the Physician Fee Schedule.
- (7) “7” – does not relate to diagnostic testing at all, rather, “7” indicates a therapy service that is not covered if furnished in a hospital by an “independently practicing” PT or OT.
- a. While not entirely clear, the term “independently practicing” probably includes a PT or OT employed by a medical practice.

- (8) "8" – indicates a service which is only covered if an abnormal smear for a hospital inpatient was interpreted. This indicator is currently only applicable to CPT code 85060, which is billed without the 26 modifier.
- (9) "9" – indicates that the PC/TC concept is not applicable to the code.
- (10) "0" – indicates that the code represents a professional service that is not divisible into separate professional and technical components.

## C. Physician Order Requirements for Diagnostic Tests

### 1. The General Rule

- a. Diagnostic tests payable under the fee schedule are only considered reasonable and necessary if ordered by a "treating physician." <42 CFR § 410.32(b)(1); *Medicare Benefit Policy Manual*, Chapter 15 § 80.6.1>
  - (i) A "treating physician" is defined as a "physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem." <42 CFR § 410.32(a); *Medicare Benefit Policy Manual*, Chapter 15 § 80.6.1>
    - (a) A non-physician practitioner operating within the scope of his/her state licensure is considered to be a treating "physician" for purposes of the physician order requirement. <42 CFR § 410.32(a)(3); *Medicare Benefit Policy Manual*, Chapter 15 § 80.6.1>
    - (b) A diagnostic radiologist would generally not qualify as a "treating physician." <*Medicare Benefit Policy Manual*, Chapter 15 § 80.6.1>

### 2. Exceptions

- a. Screening Mammography
  - (i) Screening mammography is covered (subject to certain frequency limits) without a physician order. <*Medicare Benefit Policy Manual*, Chapter 15 § 280.3; *Medicare Claims Processing Manual*, Chapter 18 § 20(A)>
- b. Follow-up Mammography
  - (i) A non-treating physician who interpreted a screening mammogram may order a follow-up diagnostic mammogram if an abnormality was detected

from the screening mammogram and the patient is still at the testing facility. <42 CFR § 410.32(a)(2); *Medicare Claims Processing Manual*, Chapter 18 § 20.6(B)>

- (a) Where a screening mammogram is followed by a diagnostic mammogram, both studies should be reported. The modifier -GG should be appended to the code for the diagnostic mammogram. <*Medicare Claims Processing Manual*, Chapter 18 §§ 20.2, 20.6(B)>

### 3. The Form of the Physician Order

- a. An order may be in the form of a written document, a telephone call, or an e-mail message. <*Medicare Claims Processing Manual*, Chapter 23 § 10.1; *Medicare Benefit Policy Manual*, Chapter 15 § 80.6.1>
- (i) However, for telephone orders, both the treating physician and the testing facility must document the phone order in their respective copies of the beneficiary's medical record. <*Medicare Claims Processing Manual*, Chapter 23 § 10.1; *Medicare Benefit Policy Manual*, Chapter 15 § 80.6.1>

## D. Physician Supervision

### 1. The General Rule

- a. All diagnostic tests must be performed under either "general," "direct" or "personal" physician supervision. <42 CFR § 410.32(b)(3); *Medicare Benefit Policy Manual*, Chapter 15 § 80>

### 2. Non-Physician Practitioners (NPPs)

- a. The 2021 Medicare Physician Fee Schedule Final Rule, finalized the COVID-19 PHE policy of NPP supervision of diagnostic testing that was set forth in the May 1, 2020, COVID -19 PHE Interim Final Rule <85 CFR 27550-27629>

- (a) Nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs) to supervise the performance of diagnostic tests. <See 410.32(b (1))>

(1) The diagnostic tests must be within the scope of practice and applicable to state law.

(2) NPPs must maintain relationships with supervising and collaborating physicians as required under Medicare statute.

- b. Historically, NPPs were not considered to be physicians for purposes of the physician supervision requirement and were only able to function as a supervising physician if the diagnostic test was personally performed.

### 3. Definition of the Three Levels of Physician Supervision

#### a. General Supervision

- (i) "General supervision" requires that the service be performed under the overall direction and control of the physician; however, the physician's physical presence is not required during the performance of the test. <42 CFR § 410.32(b)(3)(i); Medicare Benefits Policy Manual, Chapter 15 § 80>

- (a) A physician who provides general supervision must have continuing responsibility for the training of the nonphysician personnel who actually perform the test and the maintenance of the necessary equipment and supplies. <42 CFR § 410.32(b)(3)(i); Medicare Benefits Policy Manual, Chapter 15 § 80>

#### b. Direct Supervision

- (i) The definition of "direct supervision" for purposes of diagnostic testing is the same as the definition previously discussed in connection with "incident to" services. That is, the physician must be present in the office suite and immediately available to furnish assistance and direction while the test is being performed. <42 CFR § 410.32(b)(3)(ii); Medicare Benefits Policy Manual, Chapter 15 § 80>

#### c. Personal Supervision

- (i) "Personal supervision" requires that the physician be in attendance in the room while the test is being performed. <42 CFR § 410.32(b)(3)(iii); Medicare Benefits Policy Manual, Chapter 15 § 80>

### 4. Determining the Level of Physician Supervision Required for a Particular Test

- a. The Relative Value File contains a "physician supervision" indicator that indicates the required level of physician supervision for each diagnostic test. <Medicare Claims Processing Manual, Chapter 23 Addendum, MPFSDB Record Layout>

- (i) The physician supervision indicator will have one of the following values:

- (a) "01" – requires general supervision,

- (b) "02" – requires direct supervision,
- (c) "03" – requires personal supervision, ( For services rendered on or after 01/01/2019 diagnostic imaging procedures performed by a Registered Radiologist Assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists (ARRT) or a Radiology Practitioner Assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA), and is authorized to furnish the procedure under state law, may be performed under direct supervision)
- (d) "04" – physician supervision requirement does not apply when the service is furnished by a qualified, independent psychologist or a clinical psychologist, otherwise requires general supervision,
- (e) "05" – physician supervision requirement does not apply when the service is furnished by a qualified audiologist, otherwise requires direct physician supervision when furnished by a qualified technician,
- (f) "06" – service must be performed by a physician or a physical therapist who is certified by the American Board of Physical Therapy Specialties (ABPTS) as a qualified electrophysiological clinical specialist and is permitted to perform the service under state law,
- (g) "21" – service must be performed by a technician with certification under general supervision of a physician, otherwise requires direct supervision,
- (h) "22" – services may be performed by a technician with on-line real-time contact with physician.
- (i) "66" – services may be performed by a physician or by a physical therapist with ABPTS certification and certification in the specific procedure,
- (j) "6A" – supervision standards for level 66 apply; in addition, the PT with ABPTS certification may supervise another PT, but only the PT with ABPTS certification may bill,
- (k) "77" – services must be performed by a PT with ABPTS certification or by a PT without certification under the direct supervision of a physician, or by a technician with certification under general supervision of a physician,

- (l) "7A" – supervision standards for level 77 apply; in addition, the PT with ABPTS certification may supervise another PT, but only the PT with ABPTS certification may bill,
- (m) "09" – the physician supervision concept does not apply. < See *Medicare Claims Processing Manual*, Chapter 23 Addendum, MPFSDB Record Layout; *Medicare Benefits Policy Manual*, Chapter 15 § 80>

## II. Diagnostic Imaging Services

### A. Implications of Physician Specialty

- 1. Professional component radiology services may be furnished by any physician, regardless of the physician's specialty. < *Medicare Claims Processing Manual*, Chapter 13 § 20.1>

### B. Written Report Requirement

- 1. A written report must be prepared for the professional component of diagnostic imaging services. < *Medicare Claims Processing Manual*, Chapter 13 § 20.1>

### C. Multiple Procedure Payment Reduction (MPPR)

#### 1. In General

- a. Medicare has a longstanding policy to reduce payment by 50 percent for the second and subsequent *surgical* procedures performed on the same patient by the same physician or group practice in the same session, based on efficiencies in the practice expense (PE) and pre- and post-surgical physician work. CMS has been applying this concept to certain imaging procedures and physical therapy procedures as well.

#### 2. Technical Component Reduction

- a. The concept of eleven different "families" of imaging codes is retired. Now the affected imaging codes are grouped together into a single family whereby the technical component is subject to a 50% multiple procedure payment reduction when multiple technical component imaging procedures are performed during the same session. This policy became effective January 1, 2011. < *One-Time Notification Manual, Transmittal 738*>

- (i) Codes that are subject to the MPPR are identified on the Physician Fee Schedule with a multiple surgery value of "4" and an indicator of "88" in the

Diagnostic Imaging Family field. <One-Time Notification Manual, Transmittal 738>

- b. The multiple procedure payment reduction was increased to 50% starting July 1, 2010, when performed during the same session and the procedures were included within the same "family" of codes, the subsequent TC services furnished are reduced by 50 percent. <One-Time Notification Manual, Transmittal 694>
- c. When first introduced the technical component of certain subsequent diagnostic procedures was reduced by 25 percent (January 1, 2006, until June 30, 2010). <70 Fed. Reg. 70,263>
  - (i) Definitions of the Families
    - (a) The families were defined by body area, with procedures involving the same or contiguous body areas being grouped into the same family. The list of families, including the codes that fall within each family, was set forth in the physician fee schedule final rule. <73 Fed. Reg. 70,159>

### 3. Professional Component Reduction

- a. CMS expanded its multiple procedure payment reduction policy to include the professional component for diagnostic imaging procedures identified with a multiple procedure surgery value of "4" and the indicator "88" in the Diagnostic Imaging Family field. The procedures with the highest PC and TC payments will be paid for in full. The PC payment will be reduced by 5percent for subsequent procedures furnished to the same patient, by the same physician, in the same session. <MLN Matters MM7442>
- b. Note the MPPR policy began January 1, 2012, Effective January 1, 2017, this reduction will only be 5 percent, instead of 25 percent, as required by the Consolidated Appropriations Act of 2016 <MLN Matters MM9647>
- (i) Interestingly, for "operational considerations" CMS will not apply the reduction to group practices when different physicians in a group see the same patient on the same day. <MLN Matters MM7442>

#### 4. Definition of "Same Session"

- a. For purposes of the imaging multiple procedure payment reduction, the term "same session" means "one encounter where a patient could receive one or more radiological studies." <70 Fed. Reg. 70,262>
  - (i) Where multiple imaging procedures are performed for the same patient on the same day, but during separate encounters (for medical reasons), the -59 modifier should be reported. Procedures reported with the -59 modifier will not be subject to the diagnostic multiple procedure payment reduction. <70 Fed. Reg. 70,263>
    - (a) **Compliance caution** – CMS takes the position that scheduling patients for separate sessions to avoid the multiple procedure payment reduction constitutes fraud. <70 Fed. Reg. 70,263>

#### 5. Application of the Reduction

- a. When multiple imaging procedures with the Imaging Family Indicator of "88" are performed during the same session for the same patient, the payment reduction is applied as follows:
  - (i) The allowable for the technical component of the procedure with the highest fee schedule amount will be based on 100% of the fee schedule amount.
  - (ii) The allowable for the technical component of all other procedures with a multiple surgery value of "4" and a family indicator "88" will be based on 50% of the fee schedule amount.
    - (a) The technical component reimbursement cannot exceed the amount that would be paid under the outpatient prospective payment system (OPPS). <MLN Matters Article SE0665>
  - (iii) When imaging services are subject to both the MPPR and the outpatient hospital cap, then CMS will apply:
    - (iv) First, the multiple imaging adjustment, and
      - (a) Second, the outpatient cap. <MLN Matters Article SE0665>

#### 6. The Consolidated Appropriations Act of 2016 further affected radiology reductions starting in 2017 to the technical component for x-rays performed with older technology. <Public Law No: 114-113>

- (i) CMS is incentivizing healthcare providers to transition from X-ray and computed radiography to digital radiography and in the process, help lower patient exposure to ionizing radiation.
  - b. This law created a reduction in payment for organizations performing x-rays using film and computed radiography technology/cassette based imaging.
    - (i) X-rays utilizing film are subject to a 20 percent reduction which began on January 1, 2017.
    - (ii) Computed radiography technology/cassette-based imaging is currently subject to a 10 percent reduction (effective January 1, 2023).
      - (a) Historically from the effective date of January 1, 2018, through December 31, 2022, the reduction was set at seven percent. <Medicare Claims Processing Manual, Chapter 4 §§ 20.6.14 and 20.6.15>
  - c. Providers are to indicate use of older technology through modifier reporting:
    - (i) FX – X-ray taken using film
    - (ii) FY – X-ray taken using computed radiography technology/cassette-based imaging
- D. Certification for Suppliers of Advanced Diagnostic Imaging Services
1. In General
    - a. Suppliers of the technical component of certain advanced diagnostic imaging services will need to be certified by January 1, 2012, in order to be eligible for reimbursement. <One Time Notification Manual, Transmittal 727>
  2. Services Included
    - a. Advanced diagnostic imaging services specifically included in this provision are:
      - (i) Diagnostic magnetic resonance imaging (MRI),
      - (ii) Computed tomography (CT), and
      - (iii) Nuclear medicine imaging, such as positron emission tomography (PET).  
<One Time Notification Manual, Transmittal 727>
  3. Excluded Services

- a. Practitioners billing only for the professional interpretation of the advanced diagnostic imaging services are not required to be accredited.
- b. Services that are specifically excluded from the accreditation requirement are:
  - (i) X-ray,
  - (ii) Ultrasound,
  - (iii) Fluoroscopy services, and
  - (iv) Mammography <One Time Notification Manual, Transmittal 727>

#### 4. Accrediting Organizations

- a. Suppliers may seek accreditation from one of the four organizations approved by CMS:
  - (i) American College of Radiology (ACR)
  - (ii) Intersocietal Accreditation Commission (IAC)
  - (iii) The Joint Commission (TJC) <One Time Notification Manual, Transmittal 727>
  - (iv) RadSite <CMS List of ADI Accrediting Organizations>

#### E. Computed Tomography (CT) Equipment Standards

- 1. Per the Protecting Access to Medicare Act of 2014 (PAMA), payments for the technical component of CT Scans furnished with equipment that does not meet the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013 must be reduced effective January 1, 2016. <80 Fed Reg, November 16, 2015; MLN Matter MM9250>
  - a. Reduction in payment is 5% in 2016; 15% in 2017 & subsequent years
- 2. HCPCS Level II modifier to be used to indicate the service is performed using equipment that does not meet the NEMA Standard:
  - a. –CT - Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard

#### F. Supervision and Interpretation ("S&I") Codes

## 1. Reporting S&I Codes

- a. Some radiology procedure codes (generally, codes for “interventional” procedures”) contain the phrase “supervision and interpretation” in the code description. Radiologic S&I codes are used to describe the personal supervision of the performance of the radiologic portion of a procedure by one or more physicians and the interpretation of the findings.
- b. For these codes, the term “supervision” refers to physician supervision during the performance of the procedure and “interpretation” refers to the review of and report on the test results. In order to bill for the supervision aspect of the procedure, the physician must be present during its performance.

## 2. Split Supervision and Interpretation

- a. If the supervision and interpretation are performed by two physicians, then each physician should bill the appropriate HCPCS code and the -52 (reduced services) modifier. <Medicare Claims Processing Manual, Chapter 13 § 80.1>

## G. Contrast

### 1. Background

- a. In some cases, contrast material (i.e., dye) is administered for radiology studies. Often, a type of contrast called low osmolar contrast media (“LOCM”) is used.

### 2. Billing for the Supply of the Contrast Material

- a. Separate payment is available under the Physician Fee Schedule for LOCM furnished to non-hospital patients. (HCPCS code Q9951). <Medicare Claims Processing Manual, Chapter 13 § 30.1.1>

## H. Mammography

### 1. Overview

- a. Billing and payment for mammography studies is generally based on the following on whether the purpose of the study was “screening” or “diagnostic”

### 2. Screening Versus Diagnostic Mammography

- a. Screening Mammography

(i) Definition

- (a) Screening mammography is mammography performed in the absence of signs and symptoms (i.e., the patient is "asymptomatic"). <42 CFR § 410.34(a)(2); Medicare Benefit Policy Manual, Chapter 15 § 280.3>

(ii) Coverage Issues

- (a) Coverage frequency depends on the patient's age. <42 CFR § 410.34(d); Medicare Benefit Policy Manual, Chapter 15 § 280.3>

(1) Age 35 - 39 – One baseline mammogram

(2) Over age 39 – One yearly mammogram, after an 11-month period has elapsed.

a. Example

- i. A 50-year-old Medicare beneficiary had a screening mammogram on January 15. She will be eligible for her next covered screening mammogram on January 1 of the following year.

(iii) Applicability of Part B Deductible and Coinsurance

- (a) Effective January 1, 2011, screening mammography services are exempt from coinsurance as well as the deductible. <*One Time Notification Manual, Transmittal 864*>

(1) Prior to January 1, 2011, screening mammography services were exempt from the deductible, however, coinsurance requirement applied. <*Medicare Claims Processing Manual, Chapter 18 § 20.3*>

(iv) Coding for Screening Mammography

(a) CPT Coding

(1) CPT Code 77067 -Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed

(b) ICD-10-CM Diagnosis Coding

- (1) Z12.31 - Encounter for screening mammogram for malignant neoplasm of breast

b. Diagnostic Mammography

(i) Definition

- (a) A mammogram is generally considered to be a “diagnostic mammogram” if:

- (1) The patient has distinct signs and symptoms for which a mammogram is indicated,
- (2) The patient has a history of breast cancer, or
- (3) The patient is asymptomatic; but, based on the patient’s history and other factors the physician considers significant, the physician’s judgment is that a diagnostic mammogram is appropriate. <42 CFR § 410.34(a)(2); Medicare Claims Processing Manual, Chapter 18 § 20(B)>

- (b) Cost-sharing is appropriate. Coinsurance and Medicare Part B deductible apply.

(c) Appropriate CPT Coding

- (1) Bilateral diagnostic mammography
  - a. Reported with CPT 77066 - Diagnostic mammography, including computer-aided detection (CAD) when performed; Bilateral); or
- (2) Unilateral Diagnostic Mammography
  - a. Reported with CPT 77065 - Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral). <Medicare Frequency Asked Questions for Mammography Services>

c. Breast Tomosynthesis

- (i) Breast tomosynthesis is an advanced form of mammography, a specific type of breast imaging that uses low-dose x-rays to detect cancer early when it is most treatable

## (a) Screening Breast Tomosynthesis

- (1) Reported with CPT 77063 – Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure)

## (b) Diagnostic Breast Tomosynthesis

- (1) Reported with HCPCS G0279 - Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)

## I. Appropriate Use Criteria in Advanced Diagnostic Imaging

*Note: Permanently Paused; in the 2024 MPFS Proposed Rule, CMS paused efforts to implement the Appropriate Use Criteria (AUC) program for reevaluation and to rescind the current AUC program regulations at 42 CFR 414.94. <88 Fed.Reg. 79261>*

1. The 2016 Medicare Physician Fee Schedule Final Rule announced the intent of CMS to implement an Appropriate Use Criteria program for Advanced Diagnostic Imaging services. The authority to do so by CMS comes from the Protecting Access to Medicare Act (PAMA). <80 Fed. Reg. November 16, 2015>
  - a. In section 1834(q)(1)(B) of PAMA, Appropriate Use Criteria are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decisions for a specific clinical condition.
  - b. Access to Medicare Act (PAMA) of 2014, Section 218(b), established a new program to increase the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries.
    - (i) Examples: computerized tomography, positron emission tomography, nuclear medicine, and magnetic resonance imaging.
    - (ii) Under this program, at the time a practitioner orders an advanced imaging service for a Medicare beneficiary, he/she will be required to consult a qualified Clinical Decision Support Mechanism (CDSM).
      - (a) CDSMs are digital tools that guide physicians to the appropriate imaging service according to clinical circumstances.
2. The 2018 Medicare Physician Fee Schedule Final Rule Finalized the following:

- a. The Medicare AUC program will begin with an educational and operations testing year in 2020, requiring physicians to start using CDSMs and reporting this information on their claims.
  - (i) CMS extended the education and operations through calendar year 2022. The AUC payment penalty phase has been suspended indefinitely at this time.
    - (a) On November 11, 2023, CMS published the following statement:
      - (1) *The payment penalty phase will not begin January 1, 2023, even if the PHE for COVID-19 ends in 2022. Until further notice, the educational and operations testing period will continue. CMS is unable to forecast when the payment penalty phase will begin.*
- b. During the education and operations testing years, CMS is proposing to pay claims for advanced diagnostic imaging services regardless of whether they correctly contain information on the required AUC consultation.
- c. CMS posted newly qualified provider-led entities and clinical decision support mechanisms in July of 2017.
  - (i) Qualified provider-led entities are permitted to develop AUC, and qualified clinical decision support mechanisms. <CMS Clinical Decision Support Mechanisms>
  - (ii) Voluntary participation period – Started July 1, 2018, and ran through 2019.
    - (a) During this time CMS collected limited information on Medicare claims to identify advanced imaging services for which consultation with appropriate use criteria took place.
    - (iii) The use of qualified clinical decision support mechanisms was credited under the Merit-Based Incentive Payment System as an improvement activity. <2018 Quality Payment Program final rule>
- d. Effective July 1, 2018 – December 31, 2019 HCPCS modifier QQ was available for use to indicate that a Qualified Clinical Decision Support Mechanism was consulted.
  - (i) HCPCS Modifier QQ - Ordering professional consulted a qualified clinical decision support mechanism for this service and the related data was provided to the furnishing professional

- (ii) A list of appropriate CPT codes for CY 2020 can be found in the MLN Matters MM11268
  - (iii) Applicable settings where consultation with CDSM is required include physician offices, hospital outpatient departments (including emergency departments), ambulatory surgical centers, independent diagnostic testing facilities, and any other provider-led outpatient setting determined appropriate by the Secretary of Health and Human Services
  - (iv) Applicable payment systems include physician fee schedule (PFS), the hospital outpatient prospective payment system (OPPS), and the ambulatory surgical center payment system. <MLN Matters 11268>
- e. Revisions to Appropriate Use Criteria (AUC) <83 Fed. Reg. 59698>
- (i) CMS recognizes certain circumstances may cause significant hardship to consult with the CDSM. Exceptions to CDSM consulting include:
    - (a) Insufficient internet access;
    - (b) Electronic health record (EHR) or clinical decision support mechanism (CDSM) vendor issues;
    - (c) Extreme and uncontrollable circumstances, or
    - (d) Situations in which the patient has a medical emergency.
  - (ii) Ordering professionals can self-attest to hardship status.
  - (iii) AUC consultations, when not personally performed by the ordering professional, may be performed by clinical staff under the direction of the ordering professional.
    - (a) Ordering physician/support staff may not shift CDSM consultation to the performing provider.
- f. CDSM Exception Modifiers – Effective January 2020
- (i) An exception modifier must be reported with an imaging service where circumstances prohibited consultation with the CDSM as follows:
    - (a) MA – Ordering professional is not required to consult a clinical decision support mechanism due to service being rendered to a patient with a suspected or confirmed emergency medical condition

- (b) MB - Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of insufficient internet access
  - (c) MC - Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of electronic health record or clinical decision support mechanism vendor issues
  - (d) MD - Ordering professional is not required to consult a clinical decision support mechanism due to the significant hardship exception of extreme and uncontrollable circumstances
- g. Additional CDSM Modifiers - Effective January 2020
- (i) When an Advanced Diagnostic Imaging Service is performed subsequent to consultation with a CDSM, the imaging service should be reported with the appropriate modifier as follows:
    - (a) ME – The order for this service adheres to the appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
    - (b) MF - The order for this service does not adhere to the appropriate use criteria in the qualified clinical decision support mechanism consulted by the ordering professional
    - (c) MG - The order for this service does not have appropriate use criteria in the clinical decision support mechanism consulted by the ordering professional
    - (d) MH – Unknown if ordering professional consulted a clinical decision support mechanism for this service, related information was not provided to the furnishing professional or provider
  - (ii) Services reported with modifiers, -ME, -MF, or -MG should have an additional claim line containing a "G" code reflecting which qualified CDSM was consulted.
    - (a) The "G" codes are reported on a separate line and are for reporting purposes only; therefore, no reimbursement is associated.
    - (b) Multiple "G" codes on a single claim are acceptable

- (1) G1000 - Clinical Decision Support Mechanism Applied Pathways, as defined by the Medicare Appropriate Use Criteria Program
  - (2) G1001 - Clinical Decision Support Mechanism eviCore, as defined by the Medicare Appropriate Use Criteria Program
  - (3) G1002 - Clinical Decision Support Mechanism MedCurrent, as defined by the Medicare Appropriate Use Criteria Program
  - (4) G1003 - Clinical Decision Support Mechanism Medicalis, as defined by the Medicare Appropriate Use Criteria Program
  - (5) G1004 - Clinical Decision Support Mechanism National Decision Support Company, as defined by the Medicare Appropriate Use Criteria Program
  - (6) G1005 - Clinical Decision Support Mechanism National Imaging Associates, as defined by the Medicare Appropriate Use Criteria Program
  - (7) G1006 - Clinical Decision Support Mechanism Test Appropriate, as defined by the Medicare Appropriate Use Criteria Program
  - (8) G1007 - Clinical Decision Support Mechanism AIM Specialty Health, as defined by the Medicare Appropriate Use Criteria Program
  - (9) G1008 - Clinical Decision Support Mechanism Cranberry Peak, as defined by the Medicare Appropriate Use Criteria Program
  - (10) G1009 - Clinical Decision Support Mechanism Sage Health Management Solutions, as defined by the Medicare Appropriate Use Criteria Program
  - (11) G1010 - Clinical Decision Support Mechanism Stanson, as defined by the Medicare Appropriate Use Criteria Program
  - (12) G1011 - Clinical Decision Support Mechanism, qualified tool not otherwise specified, as defined by the Medicare Appropriate Use Criteria Program
- (c) The "G" codes are for informational purposes only and should contain no charge or a nominal charge.

### III. Clinical Diagnostic Laboratory Services

## A. Clinical Laboratory Improvement Amendments ("CLIA")

### 1. Definition

- a. "CLIA" is a federal law that regulates virtually all entities that perform testing on human specimens. <42 CFR § 493.1; Medicare Claims Processing Manual, Chapter 16 § 70.1>

### 2. Importance of CLIA

- a. In general, any entity that tests human specimens and reports patient specific results, including physician offices, must register under CLIA to either obtain a CLIA "certificate" or be deemed "CLIA-exempt" in order to bill and be paid for laboratory services furnished to Medicare (or Medicaid) beneficiaries. <42 CFR § 493.3(a)>
  - (i) A CLIA-exempt laboratory is "a laboratory that has been licensed or approved by a state where CMS has determined that the state has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the state licensure program has been approved by CMS." <42 CFR § 493.2>
    - (a) While CLIA-exempt laboratories do not need to obtain a CLIA certificate, they must still register and are still subject to many of the requirements of CLIA (e.g., inspections). <42 CFR § 493.5>

### 3. CLIA Certificate Application

- a. For the most part, CMS delegates the administration of CLIA to "approved state laboratory agencies" (typically state licensing agencies). <42 CFR § 493.2>
  - (i) In order to apply for a CLIA certificate, Form CMS-116 must be submitted to the local state agency responsible for CLIA administration.

### 4. Types of CLIA Certificates

- a. Certificate of Waiver

- (i) A “certificate of waiver” is issued to laboratories that perform only CLIA “waived tests.” <42 CFR § 493.2(d)(5); Medicare Claims Processing Manual, Chapter 16 § 70.8>

(a) Definition of “Waived Tests”

- (1) Waived tests are relatively simple lab tests that:

- a. Are cleared by FDA for home use,
- b. Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or
- c. Pose no reasonable risk of harm to the patient if the test is performed incorrectly. <42 CFR § 493.15(a); Medicare Claims Processing Manual, Chapter 16 § 70.8>

- (2) A current list of CLIA waived tests is available on the CMS’s CLIA web page.

- a. Not every CPT code in the 80000 series is subject to CLIA edits. CMS maintains a list of codes in the 80000 series which are exempt from the CLIA edits. <One-Time Notification Manual, Transmittal 882>

b. Certificate for Provider-Performed Microscopy Procedures

- (i) Issued to a laboratory that performs:

- (a) Only those tests designated as provider-performed microscopy procedures, and
- (b) CLIA waived tests. <42 CFR §§ 493.2(d)(2); 413.19; Medicare Claims Processing Manual, Chapter 16 § 70.6>

c. Certificate of Registration

- (i) Issued to a laboratory that performs moderate or high complexity laboratory testing pending issuance of a Certificate of Compliance or a Certification of Accreditation. <42 CFR § 493.2(d)(4); MLN 006270, May 2023>

d. Certificate of Compliance

- (i) Issued to a laboratory that has been found to be in compliance with the CLIA requirements for applicable levels of testing. <42 CFR § 493.2(d)(1); *MLN 006270*, May 2023>

e. Certificate of Accreditation

- (i) Issued to a laboratory by a CMS approved accrediting organization whose standards at least meet, if not exceed, the applicable CLIA requirements. <42 CFR § 493.2(d)(3); *MLN 006270*, May 2023>

B. Payment for Clinical Diagnostic Laboratory Services

1. Medicare payment for clinical diagnostic laboratory services,(CLFS), including lab services furnished by physicians/practitioners, is made under the "Clinical Diagnostic Laboratory Services Fee Schedule" rather than the Physician Fee Schedule. <*Medicare Claims Processing Manual*, Chapter 16 § 20>
  - a. Not all CPT codes found in the 80000 series of the CPT Manual are considered clinical diagnostic laboratory services. Some 80000 series codes are still paid under the Physician Fee Schedule when furnished through a physician/practitioner office. <*Medicare Claims Processing Manual*, Chapter 16 § 100.2>
2. The Medicare payment amount for a diagnostic laboratory service testing is equal to the weighted median private payor rate for each test. <*MLN Fact Sheet: Clinical Laboratory Fee Schedule, MLN006818*>
  - a. The private payor rate-based CLFS began January 1, 2018.
    - (i) Ended previous geographic adjustments to CLFS payment rates.
    - (ii) Payments are based on the applicable information collected and reported. The data collection, reporting, and payment updates generally take place every three years.
      - (a) CLIA-certified laboratories that meet certain requirements are required to submit data on private payer payments for laboratory services to CMS.
    - (iii)When median private payor rates are less than previous CLFS payment for specific clinical diagnostic laboratory testing, payments will be adjusted.
      - (a) CMS regulations limit the rate reduction amounts for most CDLTs when compared to the preceding year's payment rate.

(1) For CYs 2023-2025, the reduction is limited to 15 percent. <42 *CFR* §414.507(d)>

(2) Historical reduction rates were capped at 10% in 2020, with no reduction in CYs 2021 and 2022.

### 3. Laboratory Tests are Subject to Mandatory Assignment

a. A physician, laboratory or medical group must accept assignment for laboratory tests paid under the Laboratory Fee Schedule. <*Medicare Claims Processing Manual*, Chapter 16 § 30.1>

### 4. Deductible and Coinsurance

a. Neither the annual Part B deductible, nor the usual Part B coinsurance requirement applies to the following services:

(i) Clinical laboratory tests performed by the physician, lab, or other entity paid on an assigned basis;

(ii) Specimen collection fees; or

(iii) Travel allowances related to laboratory tests. <*Medicare Claims Processing Manual*, Chapter 16 § 30.2>

## C. Billing Issues Relating to Clinical Laboratory Services Furnished by Physicians/Practitioners

### 1. CLIA Number

a. The CLIA number must be entered on the CMS-1500 Field 23. <*Medicare Claims Processing Manual*, Chapter 16 § 70.10, Chapter 26 § 10.4>

### 2. Date of Service

a. Generally, the date of service should be the date of specimen collection – not the date the test was actually performed. <*Medicare Claims Processing Manual*, Chapter 16 § 40.8>

(i) Exceptions<sup>1</sup>

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<sup>1</sup> Medicare Claims Processing Manual, Chapter 16 § 120.1 also addresses stored specimens. There is arguably some inconsistency between that section and section 40.8. Presumably, section 40.8, which was released after section 120.1, reflects current CMS policy.

(a) Stored Specimens

- (1) For specimens stored less than or equal to 30 days from the date it was collected and for chemotherapy sensitivity tests, the date of service is the date the test was performed. <Medicare Claims Processing Manual, Chapter 16 § 40.8>

(b) Archived Specimens

- (1) For archived specimens, the date of service should be the date the specimen was "obtained from the archives." <Medicare Claims Processing Manual, Chapter 16 § 40.8(A)>
- a. A specimen is considered an "archived specimen" if it was stored more than 30 days before testing. <Medicare Claims Processing Manual, Chapter 16 § 40.8(A)>

(c) Extended Collection Period

- (1) If a specimen was collected over a period that spanned two calendar days, the date of service should be the date the specimen collection ended. <Medicare Claims Processing Manual, Chapter 16 § 40.8>

(d) Advanced Diagnostic Laboratory Tests and Molecular Pathology Tests

- (1) The date of service is the date the test or service was performed. <Medicare Claims Processing Manual, Chapter 16 § 40.8(A)>

3. Repeat Testing on the Same Day

a. Limitations on Payment for Repeat Tests

- (i) Separate payment is available for repeat tests performed on the same day "only when it was necessary to obtain multiple results for clinical reasons." <Medicare Claims Processing Manual, Chapter 16 § 100.5.1>

## b. Modifier Usage

- (i) Modifiers -59 (distinct procedural service) or -91 (repeat clinical lab test) are used to indicate that a service was performed more than once on the same day for the same patient. <Medicare Claims Processing Manual, Chapter 16 § 100.5.1>
  - (a) The -91 modifier may be used to indicate that a repeat lab test was distinct or separate from a lab panel or other lab services performed on the same day and was performed to obtain subsequent reportable test values. <Medicare Contractor Beneficiary and Provider Communications Manual, Chapter 5 § 20.4.3 Example 2.a; Medicare Claims Processing Manual, Chapter 16 § 100.5>
    - (1) It appears that CMS intends for the modifier -91 to be used with services paid under the Laboratory Fee Schedule. <Medicare Claims Processing Manual, Chapter 16 § 100.5.1>
      - a. However, the -91 modifier does not appear to be limited just to services paid on the Laboratory Fee Schedule since the Medicare Contractor Beneficiary and Provider Communications Manual, Chapter 5 § 20.4 provides an example suggesting that -91 should be used with cytopathology services (which are paid under the Physician Fee Schedule rather than the Clinical Diagnostic Laboratory Fee Schedule).

## D. Organ/Disease Panels

### 1. Definition

- a. "Panels" are groups of lab tests performed together – typically using automated testing equipment. < Medicare Claims Processing Manual, Chapter 16 § 90>

### 2. Medicare Determination of What Tests Are Included in Each Panel

- a. Medicare uses the CPT manual definitions to define the tests included in each panel. < Medicare Claims Processing Manual, Chapter 16 § 90.2>
  - (i) A panel code should not be billed unless all of the tests included in the panel were performed. < Medicare Claims Processing Manual, Chapter 16 § 90.2>
    - (a) Separate payment is available for additional tests performed beyond those included on the panel. < Medicare Claims Processing Manual, Chapter 16 § 90.2>

### 3. Panels Not Covered by Medicare

- a. The following CPT panels are omitted from the Clinical Diagnostic Laboratory Fee Schedule:
  - (i) Code 80050 (general health panel)
- b. CMS appears to take the position that the omitted panel is not a Medicare benefit – presumably because they relate to preventative services. <Program Memorandum AB-97-23>
  - (i) However – Medicare may cover one or more of the individual tests included in these panels if the individual tests are medically necessary. <Program Memorandum AB-97-23; Program Memorandum AB-98-71>

### 4. Billing for Panels

- a. CMS requires the use of the panel codes on and after January 1, 2019. Prior to that, CMS allowed individual reporting of tests as long as reimbursement did not exceed the panel code fee amount. < Medicare Claims Processing Manual, Chapter 16 § 90.2>

## E. The Lab National Coverage Determinations (“NCDs”)

### 1. Definition

- a. The lab NCDs are national coverage policies for clinical diagnostic laboratory tests. <Medicare Claims Processing Manual; Chapter 16 § 120.2>
- b. The lab NCDs are set forth in a special Medicare National NCD manual for laboratory services. <CMS web site page; [www.cms.gov/medicare/coverage/coverageegeninfo/labncdsicd10](http://www.cms.gov/medicare/coverage/coverageegeninfo/labncdsicd10) >
  - (i) Although the laboratory NCD manual is available on CMS’s web site, it is not one of CMS’s internet only manuals (“IOM”). However, portions of the laboratory NCD manual are incorporated into the National Coverage Determinations Manual (Pub. 100-03), which is an IOM manual.

## 2. Scope

- a. The laboratory NCDs are national policies – Contractors may not issue or maintain local policies that are inconsistent with the laboratory NCDs. *< Medicare Claims Processing Manual; Chapter 16 § 120.2>*

## 3. Diagnosis Codes

- a. There are three “lists” of diagnosis codes applicable to each lab NCD.

### (i) Non-Covered ICD-10-CM Codes for All NCD Edits

(a) This is a master list set forth at the beginning of the lab NCD manual.

- (1) This list applies to all NCDs and represents diagnoses for which a laboratory test covered by an NCD will never be a covered Medicare benefit. *< Medicare Claims Processing Manual; Chapter 16 § 120.2>*

- a. It is not clear whether CMS takes the position that the list of “ICD-10-CM codes denied” also applies to laboratory tests that do not fall within the scope of one of the laboratory NCDs.

- (2) Tests performed for one of these diagnoses may be billed to the patient without an ABN. *< Medicare Claims Processing Manual One-Time Notification Transmittal 11>*

- a. If a test performed for one of these diagnoses is billed to Medicare, the test should be billed with the -GY modifier. *< Medicare Claims Processing Manual, One-Time Notification Transmittal 11>*

### (ii) ICD-10-CM Codes Covered by Medicare

(a) This list is set forth in the body of each NCD.

- (1) These codes are deemed to support medical necessity. *< Medicare Claims Processing Manual; Chapter 16 § 120.2>*

### (iii) ICD-10-CM Codes That Do Not Support Medical Necessity

(a) This list is set forth in the body of each NCD.

- (1) In many cases, this list includes all diagnosis codes not included in one of the two lists discussed above.

a. These codes represent diagnoses that generally do not support medical necessity but for which there may be exceptions. They may be billed to the patient if the patient was given a valid ABN. < *Medicare Claims Processing Manual*; Chapter 16 § 120.2 >

b. Matching Diagnosis and HCPCS Codes

(i) CMS requires the Contractors to “review all of the diagnosis codes [on the claim] in making a determination regarding medical necessity of the service.” < *Medicare Claims Processing Manual*, Chapter 16 § 120.1 >

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recapture amount will produce a reduction to the conversion factor of -0.18 percent.

Effective January 1, 2012, we implemented an MPPR of 25 percent on the professional component (PC) of advanced imaging services. Section 502(a)(2)(A) of Division O, Title V of the Consolidated Appropriations Act of 2016 (Pub. L. 114-113, enacted on December 18, 2015) added a new section 1848(b)(10) of the Act, which revises the MPPR on the professional component of imaging services from 25 percent to 5 percent, effective January 1, 2017. Section 502(a)(2)(B) of Division O, Title V of the Consolidated Appropriations Act of 2016 added a new subclause at section 1848(c)(2)(B)(v)(XI) which exempts the MPPR reductions attributable to the new 5 percent MPPR on the PC of imaging from the PFS budget neutrality provision. However, the provision does not exempt the change attributable to the 25 percent MPPR from PFS budget neutrality. Therefore, for CY 2017 we must calculate PFS rates in a manner that exempts the 5 percent MPPR from budget neutrality but ensures that the elimination of the 25 percent MPPR is

included in PFS budget neutrality. We note that the application of the 25 percent MPPR has been applied in a budget neutral fashion to date.

The CY 2017 final PFS rates exclude the 5 percent MPPR for the professional component of imaging services by calculating the rates as if the discount does not occur, consistent with our approach to other discounts that occur outside of PFS budget neutrality. In order to implement the change from the 25 percent discount in 2016 to the 5 percent discount in 2017 within PFS budget neutrality, we measured the difference in total RVUs for the relevant services, assuming an MPPR of 25 percent and the total RVUs for the same services without an MPPR, and then applied that difference as an adjustment to the conversion factor to account for the increased expenditures attributable to the change, within PFS budget neutrality. This approach is consistent with the statutory provision that requires the 5 percent MPPR to be implemented outside of PFS budget neutrality.

To calculate the final conversion factor for this year, we multiplied the product of the current year conversion factor and the update adjustment factor

by the target recapture amount, the budget neutrality adjustment and the imaging MPPR adjustment described in the preceding paragraphs. We estimate the CY 2017 PFS conversion factor to be 35.8887, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under section 1848(d)(18) of the Act, the adjustment due to the non-budget neutral 5 percent MPPR for the professional component of imaging services, and the -0.18 percent target recapture amount required under section 1848(c)(2)(O)(iv) of the Act and described above. We estimate the CY 2017 anesthesia conversion factor to be 22.0454, which reflects the same overall PFS adjustments.

We note that the proposed RVU budget neutrality adjustment was negative, due to the estimated overall increases in proposed RVUs relative to 2016. However, because we did not finalize the proposed changes to make separate payment for the additional resource costs involved in mobility impairment services, we are finalizing an overall decrease in RVUs relative to 2016. This results in an RVU budget neutrality adjustment that is positive.

TABLE 50—CALCULATION OF THE FINAL CY 2017 PFS CONVERSION FACTOR

Conversion factor in effect in CY 2016		35.8043
Update Factor	0.50 percent (1.0050).	
CY 2017 RVU Budget Neutrality Adjustment	-0.013 percent (0.99987).	
CY 2017 Target Recapture Amount	-0.18 percent (0.9982).	
CY 2017 Imaging MPPR Adjustment	-0.07 percent (0.9993).	
CY 2017 Conversion Factor		35.8887

TABLE 51—CALCULATION OF THE FINAL CY 2017 ANESTHESIA CONVERSION FACTOR (CM ESTIMATE)

CY 2016 National Average Anesthesia Conversion Factor		21.9935
Update Factor	0.50 percent (1.0050).	
CY 2017 RVU Budget Neutrality Adjustment	0.013 percent (0.99987).	
CY 2017 Target Recapture Amount	-0.18 percent (0.9982).	
CY 2017 Imaging MPPR Adjustment	-0.07 percent (0.9993).	
CY 2017 Conversion Factor		22.0454

Table 52 shows the payment impact on PFS services of the proposals contained in this final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues would be different from those shown in Table 52 (CY 2017 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 52.

- *Column A (Specialty):* Identifies the specialty for which data are shown.

- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2015 utilization and CY 2016 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.

- *Column C (Impact of Work RVU Changes):* This column shows the

estimated CY 2017 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.

- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2017 impact on total allowed charges of the changes in the PE RVUs.

- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2017 impact on total allowed charges of the changes in the MP RVUs, which are primarily driven

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



MLN Matters® Number: MM9647

Related Change Request (CR) #: CR 9647

Related CR Release Date: August 5, 2016

Effective Date: January 1, 2017

Related CR Transmittal #: R3578CP

Implementation Date: January 3, 2017

## Multiple Procedure Payment Reduction (MPPR) on the Professional Component (PC) of Certain Diagnostic Imaging Procedures

### Provider Types Affected

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This MLN Matters® Article is intended for physicians, providers, and clinical diagnostic laboratories, submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

### Provider Action Needed

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Change Request (CR) 9647 informs providers that Section 502(a)(2) of the Consolidated Appropriations Act of 2016 revised the Multiple Procedure Payment Reduction (MPPR) for the Professional Component (PC) of the second and subsequent procedures from 25 percent to 5 percent of the physician fee schedule amount. Make sure that your billing staffs are aware of these changes.

### Background

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Medicare currently applies the MPPR of 25 percent to the PC of certain diagnostic imaging procedures. The reduction applies to PC-only services, and the PC portion of global services, for the procedures with a multiple surgery value of '4' in the Medicare Fee Schedule database.

The Centers for Medicare & Medicaid Services (CMS) currently makes full payment for the PC of the highest-priced procedure and payment at 75 percent for the PC of each additional procedure when furnished by the same physician (or physician in the same group practice) to the same patient, in the same session on the same day.

Section 502(a)(2) of the Consolidated Appropriations Act of 2016 revised the MPPR for the PC of the second and subsequent procedures from 25 percent to 5 percent of the physician fee schedule amount. The MPPR on the Technical Component (TC) of imaging remains at 50 percent.

Effective January 1, 2017, MACs shall pay 95 percent of the fee schedule amount for the PC of each additional procedure furnished by the same physician (or physician in the same group practice) to the same patient, in the same session on the same day.

The current payment, and the payment as of January 1, 2017, are summarized in the example table below:

**Table 1: Current vs. Revised Payments**

	<b>Procedure 1</b>	<b>Procedure 2</b>	<b>Current Total Payment</b>	<b>Revised Total Payment</b>
<b>PC</b>	\$100	\$80	<b>\$160</b> (\$100 + (.75 x \$80))	<b>\$176</b> (\$100 + (.95 x \$80))
<b>TC</b>	\$500	\$400	<b>\$700</b> (\$500 + (.50 x \$400))	<b>\$700</b> (\$500 + (.50 x \$400))
<b>Global</b>	\$600	\$480	<b>\$860</b> (\$600 + (.75 x \$80) + (.50 x \$400))	<b>\$876</b> (\$600 + (.95 x \$80) + (.50 x \$400))

### **Additional Information**

The official instruction, CR9647 issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3578CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html>.

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 3578</b>	<b>Date: August 5, 2016</b>
	<b>Change Request 9647</b>

**SUBJECT: Multiple Procedure Payment Reduction (MPPR) on the Professional Component (PC) of Certain Diagnostic Imaging Procedures**

**I. SUMMARY OF CHANGES:** Section 502(a)(2) of the Consolidated Appropriations Act of 2016 revised the Multiple Procedure Payment Reduction (MPPR) for the Professional Component (PC) of the second and subsequent procedures from 25 percent to 5 percent of the physician fee schedule amount.

**EFFECTIVE DATE: January 1, 2017**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: January 3, 2017**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	4/250.16/Multiple Procedure Payment Reduction (MPPR) on Certain Diagnostic Imaging Procedures Rendered by Physicians

**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:**

**Business Requirements  
Manual Instruction**

## Attachment - Business Requirements

Pub. 100-04	Transmittal: 3578	Date: August 5, 2016	Change Request: 9647
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**SUBJECT: Multiple Procedure Payment Reduction (MPPR) on the Professional Component (PC) of Certain Diagnostic Imaging Procedures**

**EFFECTIVE DATE: January 1, 2017**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: January 3, 2017**

### I. GENERAL INFORMATION

**A. Background:** Medicare currently applies a multiple procedure payment reduction (MPPR) of 25 percent to the professional component (PC) of certain diagnostic imaging procedures. The reduction applies to PC only services, and the PC portion of global services, for the procedures with a multiple surgery value of '4' in the Medicare Fee Schedule database (MPFSDB).

**B. Policy:** We currently make full payment for the PC of the highest priced procedure and payment at 75 percent for the PC of each additional procedure, when furnished by the same physician (or physician in the same group practice) to the same patient, in the same session on the same day.

Section 502(a)(2) of the Consolidated Appropriations Act of 2016 revised the MPPR for the PC of the second and subsequent procedures from 25 percent to 5 percent of the physician fee schedule amount. The MPPR on the technical component (TC) of imaging remains at 50 percent.

The current payment, and payment as of January 1, 2017, are summarized in the attached example.

### II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility										
		A/B MAC		D M E	Shared- System Maintainers				Other			
		A	B		H H H	M A C	F I S S	M C S		V M S	C W F	
9647.1	For services furnished on or after dates of service January 1, 2017, contractors shall pay 95 percent of the fee schedule amount for the PC of each additional procedure furnished by the same physician (or physician in the same group practice) to the same patient, in the same session on the same day.	X	X			X						
9647.2	Contractors shall change the reduction value to 5 percent for multiple procedure indicator 4 in field 21 of the MPFSDB and apply the 5 percent reduction to the PC of services performed on or after January 1, 2017.		X			X						

Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared- System Maintainers				Other
		A	B		H H H	M A C	F I S S	M C S	
9647.3	Contractors shall identify TOB 85X with revenue codes 96x, 97x and/or 98x that contain more than one line item, same date of service with CPT/HCPCS codes assigned both a multiple procedure indicator equal to "4" and a diagnostic Imaging Family indicator "88" on the PFS Payment Policy Indicator.	X				X			
9647.3.1	For services performed on and after January 1, 2017, contractors shall pay the additional services lines at 95 percent.	X				X			

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility					
		A/B MAC			D M E	C E D I	
		A	B	H H H			
9647.4	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	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:
	See related Changes Requests 7442, 7684, and 7747.

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

## **V. CONTACTS**

**Pre-Implementation Contact(s):** Patrick Sartini, 410-786-9252 or patrick.sartini@cms.hhs.gov (payment policy contact), Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (practitioner claims processing contact), Cindy Pitts, 410-786-2222 or cindy.pitts@cms.hhs.gov (institutional claims processing contact)

**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: 1**

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**Attachment for CR 9647: Multiple Procedure Payment Reduction (MPPR) on the Professional Component (PC) of Certain Diagnostic Imaging Procedures**

*Example: Multiple Procedure Payment Reduction on the Professional Component of Certain Diagnostic Imaging Procedures*

	Procedure	Procedure	Current	Revised
	1	2	Total Payment	Total Payment
<b>PC</b>	\$100	\$80	<b>\$160</b> (\$100 + (.75 x \$80))	<b>\$176</b> (\$100 + (.95 x \$80))
<b>TC</b>	\$500	\$400	<b>\$700</b> (\$500 + (.50 x \$400))	<b>\$700</b> (\$500 + (.50 x \$400))
<b>Global</b>	\$600	\$480	<b>\$860</b> (\$600 + (.75 x \$80) + (.50 x \$400))	<b>\$876</b> (\$600 + (.95 x \$80) + (.50 x \$400))

Version 04/25/2024  
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## 250.16 - Multiple Procedure Payment Reduction (MPPR) on Certain Diagnostic Imaging Procedures Rendered by Physicians

*(Rev. 3578, Issued: 08-05 Effective: 01-01-17, Implementation: 01-03-17)*

Diagnostic imaging procedures rendered by a physician that has reassigned their billing rights to a Method II CAH are payable by Medicare when the procedures are eligible and billed on type of bill 85x with revenue code (RC) 096x, 097x and/or 098x.

 The MPPR on diagnostic imaging applies when multiple services are furnished by the same physician to the same patient in the same session on the same day. Full payment is made for each service with the highest payment under the MPFS. *Effective for dates of services on or after January 1, 2012, payment is made at 75 percent for each subsequent service; and effective for dates of services on or after January 1, 2017, payment is made at 95 percent for each subsequent service.*

Version 04/25/2024  
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<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 738</b>	<b>Date: July 30, 2010</b>
	<b>Change Request 6993</b>

**NOTE: This Transmittal is no longer sensitive and is being re-communicated November 17, 2010 . The Transmittal Number, date of Transmittal and all other information remain the same. This instruction may now be posted to the Internet.**

**SUBJECT: Multiple Procedure Payment Reduction (MPPR) on the Technical Component (TC) of Certain Diagnostic Imaging Procedures**

**I. SUMMARY OF CHANGES:** Section 3134 of the Affordable Care Act added section 1848(c)(2)(K) of the Social Security Act which specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service. As a step in implementing this provision, Medicare is making a change to the MPPR on the TC of certain diagnostic imaging procedures. Specifically, we are consolidating the existing eleven families of codes into a single family. This policy is discussed in the CY 2011 physician fee schedule proposed rule published on July 13, 2010. This advanced notice is provided so contractors can begin making the necessary systems changes for the policy to go in effect January 1, 2011.

**EFFECTIVE DATE: \*January 1, 2011**  
**IMPLEMENTATION DATE: January 3, 2011**

*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-

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**  
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

# Attachment – One-Time Notification

Pub. 100-20	Transmittal: 738	Date: July 30, 2010	Change Request: 6993
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**NOTE: This Transmittal is no longer sensitive and is being re-communicated November 17, 2010. The Transmittal Number, date of Transmittal and all other information remain the same. This instruction may now be posted to the Internet.**

**SUBJECT: Multiple Procedure Payment Reduction (MPPR) on the Technical Component (TC) of Certain Diagnostic Imaging Procedures**

**Effective Date:** January 1, 2011

**Implementation Date:** January 3, 2011

## I. GENERAL INFORMATION

**A. Background:** Section 3134 of the Affordable Care Act added section 1848(c)(2)(K) of the Social Security Act which specifies that the Secretary shall identify potentially misvalued codes by examining multiple codes that are frequently billed in conjunction with furnishing a single service. As a step in implementing this provision, Medicare is making a change to the MPPR on the TC of certain diagnostic imaging procedures. Specifically, we are consolidating the existing 11 families of codes into a single family. This policy is discussed in the CY 2011 physician fee schedule proposed rule published on July 13, 2010, and may change based on analysis of public comments. **This advanced notice is provided so contractors can begin making the necessary systems changes for the policy to go in effect January 1, 2011.**

**B. Policy:** Currently, the MPPR on diagnostic imaging services applies only to contiguous body parts, i.e., within a family of codes, not across families. For example, the reduction does not apply to an MRI of the brain (CPT 70552) in code family 5, when performed during the same session, on the same day, as an MRI of the neck and spine (CPT 72142) in code family 6.

⚙️ We are consolidating the existing 11 advanced imaging families into one family. Therefore, the reductions apply when two or more services on the list are furnished to the same patient in a single session. The complete list of codes subject to the MPPR on diagnostic imaging is in Attachment 1.

⚙️ The MPPR on diagnostic imaging continues to apply to TC only services, and the TC portion of global services. The MPPR does not apply to the professional component services. We continue to make the full TC payment for the procedure with the highest priced TC and payment at 50 percent each for the TC of each additional procedure on the same patient in the same session.

Contractors shall note that although the other family of code indicators continues to be valued, no codes will populate these other families in the January 1, 2011, physician fee schedule.

To accommodate implementation of this new proposal, the 2011 Medicare Physician Fee Schedule layout will have an additional change. The change is:

⚙️ A new diagnostic family indicator of '88' which will denote those services subject to the diagnostic imaging reduction.

**II. BUSINESS REQUIREMENTS TABLE**

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M M A C	F I	C A R I E R	R H I	Shared-System Maintainers				O T H E R
						F I S S	M I C S	V M S	C M W F		
6993.1	Contractors shall use the diagnostic imaging family value of "88" to identify services subject to the reduction of the TC of diagnostic imaging services on the 2011 Medicare Physician Fee Schedule Data Base (MPFSDB) layout.	X			X			X			
6993.2	For services on or after January 1, 2011, contractors shall apply the multiple procedure reduction to the TC fee on claims for all diagnostic imaging services with a value of "88" on the MPFSDB layout.	X			X			X			

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M M A C	F I	C A R I E R	R H I	Shared-System Maintainers				O T H E R
						F I S S	M I C S	V M S	C M W F		
6993.3	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> when this CR is no longer Sensitive and Controversial. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X						

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-20 One-Time Notification</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 694</b>	<b>Date: May 7, 2010</b>
	<b>Change Request 6965</b>

**SUBJECT: Multiple Procedure Payment Reduction (MPPR) on the Technical Component (TC) of Certain Diagnostic Imaging Procedures**

**I. SUMMARY OF CHANGES:** Reduction on the TC of certain multiple imaging procedures is increased from 25 percent to 50 percent.

**EFFECTIVE DATE: \*July 1, 2010**

**IMPLEMENTATION DATE: July 6, 2010**

*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.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
N/A	

**III. FUNDING:**

**For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:**

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

**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:**

**One-Time Notification**

*\*Unless otherwise specified, the effective date is the date of service.*

## Attachment – One-Time Notification

Pub. 100-20	Transmittal: 694	Date: May 7, 2010	Change Request: 6965
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**SUBJECT: Multiple Procedure Payment Reduction (MPPR) on the Technical Component (TC) of Certain Diagnostic Imaging Procedures**

**EFFECTIVE DATE:** July 1, 2010

**IMPLEMENTATION DATE:** July 6, 2010

### I. GENERAL INFORMATION

**A. Background:** Medicare currently applies a multiple procedure payment reduction (MPPR) of 25 percent to the technical component (TC) of certain diagnostic imaging procedures. The reduction applies to TC only services, and the TC portion of global services, for the procedures with a multiple surgery value of '4' in the Medicare Fee Schedule database. The MPPR does not apply to the professional component (PC) or to the PC portion of global services. The 11 families of imaging codes to which this policy applies are established according to modality (computed tomography (CT), magnetic resonance imaging (MRI), and ultrasound) and body area. The reduction applies only to more than one procedure performed in a single imaging session on contiguous body parts, i.e., within a family of codes, not across families. For example, the reduction would not apply to an MRI of the brain (CPT 70552) in code family 5 (MRI/MRA Head/Brain/Neck), when performed during the same session, on the same day, as an MRI of the neck and spine (CPT 72142) in code family 6 (MRI/MRA Spine).

Field 33E contains the Diagnostic Imaging Family Indicator. This character field identifies the applicable diagnostic service family for those HCPCS codes with a multiple surgery indicator of '4'. For the global and TC portions of the HCPCS codes subject to this policy, this field contains values of '01' through '11', which corresponds with the established family definitions. For those services not subject to this policy, including the PC portion of the applicable HCPCS codes, the value is '99'.

**B. Policy:** We currently make full payment for the TC of the highest priced procedure and payment at 75 percent for the TC of each additional procedure, when performed during the same session on the same day.

Section 3135(b) of the Patient Protection and Affordable Care Act of 2009 (PPACA) reduces payment for TC of the second and subsequent procedures from 75 percent to 50 percent of the physician fee schedule amount.

The current payment and payment as of July 1, 2010 are summarized below in the following example:

	Procedure 1	Procedure 2	Current Total Payment	Revised Total Payment
PC	\$100	\$80	\$180 (no reduction)	\$180 (no reduction)
TC	\$500	\$400	\$800 (((\$500 + (.75 x \$400)))	\$700 (((\$500 + (.5 x \$400)))
Global	\$600	\$480	\$980 (((\$600 + \$480-\$400) + (.75 x \$400))	\$880 (((\$600 + (\$480-\$400) + (.5 x \$400))

**II. BUSINESS REQUIREMENTS TABLE**

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B  M A C	D M E  M A C	F I  M A C	C A R R I E R	R H R I  I E R	Shared-System Maintainers			
					FI S S	M C S	V M S	C W F		
6965.1	For services furnished on or after dates of service July 1, 2010, contractors shall pay 50 percent of the fee schedule amount for the TC of each additional procedure in the SAME family when performed during the same session on the same day.	X			X					
6965.2	Contractors shall change the reduction value to 50 percent for multiple procedure indicator 4 in field 21 of the MPFSDB and apply the 50 percent reduction to the TC of services performed on or after July 1, 2010.	X			X					

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B  M A C	D M E  M A C	F I  M A C	C A R R I E R	R H R I  I E R	Shared-System Maintainers			
					FI S S	M C S	V M S	C W F		
6965.3	A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X					

*Response:* The CMS Internet-Only Manual (Publication 100–2, chapter 15, section 40.12) currently provides Medicare's carriers with standardized guidelines regarding the notice to physicians and practitioners, and the actions to take, in cases of failure to maintain opt out status.

We are finalizing our proposed changes to § 405.435 (b) and adding new paragraph (d) as proposed.

#### J. Multiple Procedure Payment Reduction for Diagnostic Imaging

As explained in the August 8, 2005 proposed rule (70 FR 45849), diagnostic imaging procedures are priced in the following three ways:

- The professional component (PC) represents the physician work, that is, the interpretation.
- The technical component (TC) represents PE, that is, clinical staff, supplies, and equipment.
- The global service represents both PC and TC.

Under the resource-based PE methodology, specific PE inputs of clinical labor, supplies, and equipment are used to calculate PE RVUs for each individual service. We do not believe these same inputs are needed to perform subsequent procedures. When multiple images are taken in a single session, most of the clinical labor activities and most supplies are not performed or furnished twice. In addition, equipment time and indirect costs are allocated based on clinical labor time; therefore, these inputs should be reduced accordingly. Excluding these PE inputs, which we believe are duplicative, supports a 50 percent reduction in the payment for the TC of subsequent procedures. A reduction of 50 percent is also currently used in the multiple procedure payment reduction for surgery, which has been a longstanding policy.

Therefore, we proposed extending the multiple procedure payment reduction to the TC of specific procedures listed in Table 29 of the August 8, 2005 proposed rule (70 FR 45850). Table 29 identified 11 families of imaging procedures by imaging modality (ultrasound, CT and computed tomographic angiography (CTA), MRI and magnetic resonance angiography (MRA)), and contiguous body area (for example, CT and CTA of Chest/Thorax/Abdomen/Pelvis). We proposed applying the reduction only to procedures involving contiguous body areas within a family of codes, not across families, and to those multiple procedures that were provided in one session. We also proposed only to apply the multiple procedure payment

reduction to the TC of certain procedures because, while we believe there may be some reduction in physician work associated with the performance of multiple diagnostic imaging procedures on contiguous body areas, we have no specific plans to extend the proposal to the PC. In addition, since the global service payment equals the combined PC and TC components, when the global service code is billed for these procedures, the TC would be reduced to the same as above, but the PC would be paid in full. We proposed making full payment for the TC of the highest priced procedure and payment at 50 percent of the TC for each additional procedure.

*Comment:* Several commenters supported our proposal, and described it as appropriate, reasonable, justified, rational, and consistent with the private sector. One commenter suggested extending the proposal to the professional component. Two other commenters stated that it should not be applied to the professional component. One commenter suggested applying the reduction to noncontiguous body areas imaged using the same modality. Another commenter indicated an understanding of the rationale for the proposal but did not want it extended to traditional radiographs.

*Response:* We appreciate the commenters' support. We currently have no plans to extend our proposal to incorporate the commenters' suggestions (that is, to include noncontiguous body areas, other radiologic examinations, or the professional component of imaging services). We are not certain whether and to what degree a multiple procedure payment reduction policy would be appropriate in these types of situations.

*Comment:* Several commenters opposed our proposal on the basis that diagnostic imaging is not comparable to surgery. For example, they noted that diagnostic imaging is not paid as part of a global package of services; its pre and post activities and resources are typically not as extensive as those required for surgery, and so should comprise a much smaller portion of the payment than for surgery; and it is highly capital intensive compared to surgery. One commenter stated that nuclear medicine procedures were inappropriately discounted and should not serve as precedent for discounting diagnostic imaging procedures.

*Response:* We agree that diagnostic imaging procedures are not comparable to surgical procedures and did not base the development of the multiple imaging procedure payment reduction policy on specific comparisons with the

reductions applicable to multiple surgical procedures. Instead, with findings from the MedPAC recommendation about a multiple imaging procedure reduction, detailed information regarding current imaging reduction payment policies in the private insurance industry, and our analysis of PE data, we believe that the rationale for the proposed reduction is sound. The 50 percent reduction was specifically founded upon well-established and professionally accepted data we examined from the PEAC, as described below, and was not based simply on the fact that a 50 percent reduction is applied to multiple surgical procedures. In addition, the reduction for six nuclear medicine procedures has been in effect for 11 years. During that time, we have received no evidence to indicate that it is not appropriate. Nevertheless, we did not base our multiple imaging procedure reduction policy on comparisons with nuclear medicine procedures.

*Comment:* Numerous commenters agreed that some clinical labor activities, supplies, and equipment are not duplicated for subsequent procedures. Other commenters indicated exactly the opposite (that is, that these items, including some portion of scanning time, are duplicated). In addition, some commenters indicated that where equipment adjustments are required between studies, clinical labor time could actually increase when multiple imaging procedures are performed on the same patient during a single session.

The majority of commenters agreed that there are some efficiencies when multiple procedures are performed but disagreed that all the activities we listed above are never duplicated. Therefore, they disagreed that the efficiencies achieved in subsequent procedures support a 50 percent reduction. Many commenters indicated that a 50 percent reduction is arbitrary and that we provided no supporting data. Several commenters suggested that the reduction should be somewhere between 5 and 25 percent. The ACR offered several suggestions on the relative level of reduction among families of procedures, for example, that the reduction for the procedures in family four should be less than for family two; and that the reduction for procedures in family seven should be less than for family two, but greater than for family four. However, they provided no specific percentages for the reductions in each family.

A few commenters recommended varying the percentage reduction by modality because efficiencies are not

uniform across all families of procedures. Two commenters indicated that the proposal was inconsistent with the mandate to make resource-based PE payments. Specific comments included the following:

- For ultrasound procedures, all clinical labor activities except for greeting the patient, are duplicated.
- For some CTs, repositioning the patient is necessary. Some CTs require multi-phasic contrast injections that are separately scanned.
- For CTs, MRIs and MRAs, the number of prior exams for review before the studies are performed has increased significantly.
- Some CTs, CTAs, MRIs, and MRAs require more images, slices or pulse sequences.
- For brain MRIs and neck MRAs, it is necessary to remove the patient; change from a head coil to a neurovascular coil; retune the coil; enter multiple new scan parameters; reposition the patient; and run a new set of pulse sequences. The patient often requests a break between procedures.

Several commenters recommended delaying implementation of the proposal for 1 year pending further study. Their reasons included: postponing until the PE inputs are fully implemented and clearly defined; deferring until the entire PFS methodology is reassessed; and delaying until MedPAC's other imaging study recommendations are implemented. Two commenters suggested that we phase-in the reduction. The ACR offered to work with CMS to reexamine the procedures subject to the reduction; reconfigure the families of procedures; and, determine appropriate reductions based on modality family.

*Response:* We indicated in the proposed rule that the following activities are not duplicated for subsequent procedures:

- Greeting the patient.
- Positioning and escorting the patient.
- Providing education and obtaining consent.
- Retrieving prior exams.
- Setting up the IV.
- Preparing and cleaning the room.

In addition, we consider supplies, with the exception of film, are not duplicated for subsequent procedures. Therefore, the 50 percent reduction for subsequent procedures is based on eliminating the time for the clinical labor activities noted above, plus supplies, with the exception of film. We do not assume any reduction in procedure (scanning) time or equipment for subsequent procedures. However, as noted in the proposed rule, equipment,

time, and indirect costs are allocated based on clinical labor time; therefore, these inputs were reduced accordingly.

The 50 percent reduction was determined based on the examination of multiple pairs of procedure codes from the families representing all modalities (that is, ultrasound, CT/CTA, and MRI/MRA studies) that were frequently performed on a single day based on historical claims data. Using PE input data provided by the RUC, we factored out the clinical staff minutes for the activities we indicated are not duplicated for subsequent procedures, and the supplies, other than film, which we consider are not duplicated for subsequent procedures. As noted previously, equipment time and indirect costs are allocated based on clinical labor time; therefore, these inputs were reduced accordingly. Removing the PE inputs for activities that are not duplicated, and adjusting the equipment time and indirect costs for the individual pairs of procedures studied, supports payment reductions ranging from 40 to 59 percent for the subsequent services. Because we found a relatively narrow range of percentage payment reductions across modalities and families, and taking into consideration that we did not eliminate any duplicative image acquisition time for subsequent procedures in our analysis, we decided that an across-the-board reduction for all 11 families of 50 percent (which is approximately the midpoint of the range established through our analysis) was both justified and conservative. We believe this payment reduction policy represents an appropriate reduction for the typical delivery of multiple imaging services in all 11 families. Because the reduction is based on eliminating the specific practice expense inputs that are not duplicated, we believe the proposal is consistent with the resource-based practice expense methodology.

While various alternative reduction percentages were suggested, no evidence was presented to support specific alternative percentages. However, we recognize that many commenters raised significant objections and we appreciate their comments indicating their specific concerns regarding the appropriate reductions for each family and specific combinations of services within families.

To allow for a transition of the changes in payments for these services attributable to this reduction policy, and provide a further opportunity for comment, we have decided to phase-in the policy over 2 years. We will implement a 25 percent payment

reduction in CY 2006 and a 50 percent reduction for all 11 families in CY 2007 for all code families, unless we find upon further review during the upcoming year that modifications to this policy are appropriate. To enhance our review, we are soliciting, from providers of diagnostic imaging services, comprehensive data regarding the efficiencies associated with different combinations of imaging services in the 11 families. We welcome the opportunity to have other discussions with the physician community on these issues.

*Comment:* One commenter noted that a patient having both a pelvic and transvaginal ultrasound often needs a break between procedures and requires repositioning, along with the use of a different probe for the second study. The commenter also noted that breast and pelvic ultrasounds are often performed in different locations and by different physicians.

*Response:* The commenter has raised some serious questions concerning whether any payment reduction is appropriate for the procedures indicated. Therefore, we have decided to delete transvaginal ultrasound and ultrasound of the breast(s) (CPT codes 76830 and 76645, respectively) from the list of procedures in family one subject to the payment reduction, pending further study. We believe there may be common clinical scenarios where these services are provided in combination with other ultrasound studies where payment reduction may not be appropriate. These typical efficiencies associated with these services when provided in combination with other studies in family one require further study.

*Comment:* Many commenters asked how "single session" is defined and what mechanism will be used to distinguish single and multiple sessions. One commenter indicated that multiple procedures are frequently performed in separate rooms within the radiology department or in different areas within the hospital. In these cases, the patient must be transported from one room to another and the process restarted. One commenter noted the potential for abuse by self-referring physicians writing separate prescriptions for studies on different days. Another commenter indicated that the proposal will force providers to schedule further studies on additional days.

*Response:* We consider a single session to be one encounter where a patient could receive one or more radiological studies. If more than one of the imaging services in a single family

is provided to the patient during one encounter, then this would constitute a single session and the lower-priced procedure(s) would be reduced. On the other hand, if a patient has a separate encounter on the same day for a medically necessary reason and receives a second imaging service from the same family, we consider these multiple studies in the same family on the same day to be provided in separate sessions. In the latter case, we have established that the physician should use modifier -59 to indicate multiple sessions, and that the multiple procedure reduction does not apply. Medicare carriers will establish edits to ensure that separate sessions are not inappropriately scheduled for contiguous body area imaging in attempts to bypass the reduction. Use of the modifier where not medically necessary in order to bypass the payment reduction constitutes fraud.

*Comment:* One commenter suggested that the proposal required multiple body area imaging whenever a procedure in a particular family was performed, resulting in unnecessary imaging. Another commenter stated that grouping procedures to justify lower

reimbursement provides no medical or monetary benefit and is detrimental to patient care.

*Response:* It appears the commenters have misinterpreted our proposal. The proposal in no way requires the performance of unnecessary multiple imaging procedures when only a single study is medically necessary. The families of procedures are based on claims data indicating that these procedures are often done in combination, most likely in a single session. We believe that the payment reduction for the lower-priced imaging procedures from one family performed on contiguous body areas provides the most appropriate payments for the services provided.

*Comment:* A few commenters recommended that we apply the budget neutrality adjustment only to PE RVUs and not to work RVUs.

*Response:* The commenters are correct that, because the payment reduction applies only to PE RVUs, the savings should likewise only apply to PE RVUs. We agree with this comment and have made the necessary adjustment.

*Comment:* One commenter indicated that we should request a statutory

change to exempt the proposal from budget neutrality.

*Response:* We believe it is up to the Congress to decide whether it wants to make adjustments to the application of budget neutrality. We have no plans to request this change.

*Final Decision*

We have revised our proposal as follows:

- Phase in the payment reduction, with a 25 percent reduction in CY 2006 and a 50 percent reduction in CY 2007. Our review of the multiple imaging payment reduction policy will be ongoing.
  - Deleting CPT codes 76830 and 76645 from the list of procedures in family one subject to the reduction, pending further study.
  - Applying the budget neutrality adjustment only to PE RVUs, rather than to both work and PE RVUs.

An example of the current and CY 2006 payments is summarized in Table 26, and the revised lists of procedures subject to the reduction, are set forth in Table 27:

TABLE 26.—EXAMPLE OF PAYMENTS

	Procedure 1 74183	Procedure 2 72196	Current total payment	CY 2006 total payment	CY 2006 payment calculation
PC .....	\$117.00	\$90.00	\$207.00	\$207.00	no reduction.
TC .....	978.00	529.00	1,507.00	1,374.75	978 + (.75 × \$529).
Global .....	1,095.00	619.00	1,714.00	1,581.75	\$207 + \$978 + (0.75 × \$529).

BILLING CODE 4120-01-U

Version 01/2005  
Check for updates

## Attachment – One-Time Notification

Pub. 100-20	Transmittal: 727	Date: July 9, 2010	Change Request: 6912
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**Transmittal 725, dated July 2, 2010 is rescinded and replaced by Transmittal 727, dated July 9, 2010. The implementation date and July 2010 reporting requirements are being changed in order to give contractors sufficient time to mail the notification letters to the affected providers. Additionally, Code 72200 is being removed from the list of CPT codes because it is a standard x-ray code and is not a code used for advanced diagnostic imaging services. All other information remains the same.**

**SUBJECT: Mailing To All Individual Practitioners, Medical Groups and Clinics and Independent Diagnostic Testing Facilities (IDTF) Who Are Billing or Have Billed For Advanced Diagnostic Imaging Services**

**Effective Date: August 2, 2010**

**Implementation Date: August 13, 2010**

### I. GENERAL INFORMATION

**A. Background:** The Centers for Medicare & Medicaid Services (CMS) and its Medicare carriers and Medicare Administrative Contractors (A/B MACs) provide general outreach to physicians, non-physician practitioners and other provider and supplier types about their enrollment and reporting responsibilities. The attached letter will inform enrolled physicians, non-physician practitioners and independent diagnostic testing facilities (IDTFs) about the need to become accredited to continue to furnish advanced diagnostic imaging services to Medicare beneficiaries on or after January 1, 2012.

**B. Policy:** Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1834(e) of the Social Security Act and required the Secretary to designate organizations to accredit suppliers, including but not limited to physicians, non-physician practitioners and Independent Diagnostic Testing Facilities, that furnish the technical component (TC) of advanced diagnostic imaging services. MIPPA specifically defines advanced diagnostic imaging procedures as including diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging such as positron emission tomography (PET). The law also authorizes the Secretary to specify other diagnostic imaging services in consultation with physician specialty organizations and other stakeholders. MIPPA expressly excludes from the accreditation requirement x-ray, ultrasound, and fluoroscopy procedures. The law also excludes from the CMS accreditation requirement diagnostic and screening mammography which are subject to quality oversight by the Food and Drug Administration under the Mammography Quality Standards Act.

### II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement*

Number	Requirement	Responsibility (place an "X" in each applicable column)						
		A	D	F	C	R	Shared-System Maintainers	OTH ER
		/	M	I	A	H		
		B	E		R	H		

		M A C	M A C		R I E R	I	F I S S	M C S	V M S	C W F	
6912.1	Contractors shall send the attached letter 5 times to enrolled physicians, non-physician practitioners, including single and multi-specialty clinics, and IDTFs who have billed the Medicare program for advanced diagnostic testing services (see attached related CPT Codes) within the preceding six month period and continues to have Medicare billing privileges with the contractor.	X			X						
6912.1.1	The mailings shall occur in August and October of 2010 and January, April and July of 2011.	X			X						
6912.1.2	When more than one physician or non-physician practitioner is operating within a group, such as a single specialty or multispecialty clinic, only the group shall receive the letter, not each of the individual physicians or non-physician practitioners working for the group.	X			X						
6912.1.3	If any additional suppliers not listed above submit claims for advanced diagnostic testing during this initiative, the contractor shall include that supplier in the next quarterly mailing.	X			X						
6912.2	Contractors shall not mail the attached letter to any supplier with an inactive Medicare billing status.	X			X						
6912.3	Contractors shall use the Pay To or Practice Location address found in the Multi-Carrier System (MCS) when mailing this letter to a physician, non-physician practitioner or IDTF with approved PECOS enrollment record.	X			X						
6912.3.1	Contractors shall retrieve and use the Pay To or Practice Location address found in the Multi-Carrier System for suppliers described above furnishing advance diagnostic testing services that do not have an enrollment record in PECOS.	X			X						
6912.3.2	To simplify operations, the contractor shall extract all addresses for these mailings from the MCS.	X			X						
6912.4	Contractors shall reproduce the attached letter on their own Medicare letterhead and mail in standard envelopes.	X			X						
6912.4.1	Contractors shall complete the letter with the appropriate date, name, address, contact and signature prior to mailing.	X			X						
6912.5	Contractors shall not take any action for returned letters outside of placing them in the provider file.	X			X						
6912.6	Contractors shall complete the first mailing by August 13, 2010 and each subsequent mailing within 10 days of the calendar quarter through July 2011.	X			X						

## III. PROVIDER EDUCATION TABLE

 Supplier Billed Advanced Medical Imaging CPT codes for Section 135 (a) of the MIPPA to Receive Accreditation Requirement Notification Letter

70336	70540	71250	72125	73200	74150
70450	70542	71260	72126	73201	74160
70460	70543	71270	72127	73202	74170
70470	70544	71275	72128	73206	74175
70480	70545	71550	72129	73218	74181
70481	70546	71551	72130	73219	74182
70482	70547	71552	72131	73220	74183
70486	70548	71555	72132	73221	74185
70487	70549		72133	73222	
70488	70551		72141	73223	
70490	70552		72142	73225	
70491	70553		72146	73700	
70492	70554		72147	73701	
70496	70555		72148	73702	
70498	70557		72149	73706	
	70558		72156	73718	
	70559		72157	73719	
			72158	73720	
			72159	73721	
			72191	73722	
			72192	73723	
			72193	73725	
			72194		
			72195		
			72196		
			72197		
			72198		
75557	76360	77011	78000	78811	
75559	76376	77012	78001	78812	
75561	76377	77021	78003	78813	
75563	76380	77058	78006	78814	
	76390	77059	78007	78815	
	76497	77078	78010	78816	
	76498	77079	78011	78891	
			78015		
			78016		
			78018		
			78020		
			78070		
			78075		
			78099		

Letter to be sent to all enrolled suppliers (individuals, groups and IDTFs) that have billed for advanced diagnostic imaging services within the past six months. When more than one physician or non-physician practitioner is operating within a group, such as a single specialty or multispecialty clinic, only the group will receive the letter.

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[DATE]

[Supplier Name and Address]

Dear Physician/Non-Physician Practitioner/IDTF owner:

In accordance with Section 135(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), suppliers, including but not limited to physicians, non-physician practitioners and Independent Diagnostic Testing Facilities that furnish the technical component (TC) of advanced diagnostic imaging services must be accredited by January 1, 2012 in order to continue to furnish these services to Medicare beneficiaries.

Our records indicate that you have furnished advanced diagnostic imaging procedures such as diagnostic magnetic resonance imaging (MRI), computed tomography (CT), and nuclear medicine imaging such as positron emission tomography (PET) within the last six months. If you are not accredited by one of the organizations shown below by January 1, 2012, you will not be eligible to bill the Medicare program for advanced diagnostic imaging services. This letter requests that you take the necessary action to become accredited by the January 1, 2012 deadline. Since we expect it can take up to nine months from the time you initiate the accreditation process to completion, we urge you to begin the accreditation process for advanced diagnostic imaging services as soon as possible.

MIPPA expressly excludes from the accreditation requirement x-ray, ultrasound, and fluoroscopy procedures. The law also excludes from the CMS accreditation requirement diagnostic and screening mammography which are already subject to quality oversight by the Food and Drug Administration under the Mammography Quality Standards Act.

The Centers for Medicare & Medicaid Services (CMS) approved three national accreditation organizations – the American College of Radiology, the Intersocietal Accreditation Commission, and The Joint Commission - to provide accreditation services for suppliers of the TC of advanced diagnostic imaging procedures. The accreditation will apply only to the suppliers of the images themselves, and not to the physician interpreting the image. All accreditation organizations have quality standards that address the safety of the equipment as well as the safety of the patients and staff. The accrediting organization that issues your accreditation will notify Medicare once your accreditation is complete and approved.

To obtain additional information about the accreditation process, please contact the accreditation organizations shown below.

American College of Radiology (ACR)  
1891 Preston White Drive  
Reston, VA 20191-4326  
1-800-770-0145  
[www.acr.org](http://www.acr.org)

Intersocietal Accreditation Commission (IAC)  
6021 University Boulevard, Suite 500

Ellicott City, MD 21043  
800-838-2110  
[www.intersocietal.org](http://www.intersocietal.org)

The Joint Commission (TJC)  
Ambulatory Care Accreditation Program  
One Renaissance Boulevard  
Oakbrook Terrace, IL 60181  
1-630-792-5286  
[www.jointcommission.org/AdvImaging2012](http://www.jointcommission.org/AdvImaging2012)

If you have questions about this letter, contact [carrier or A/B MAC phone number/contact person].

Sincerely,

[Name of carrier or A/B MAC]

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impacts on resident training outside the context of the PHE before considering permanent implementation of the policies.

*Response:* We appreciate commenters' support of the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID-19. As we reviewed these comments, we considered the benefits and risks of finalizing the proposals. After considering the comments, we are finalizing our virtual presence and primary care exception policies for residency training sites that are located outside of an MSA. We are finalizing our resident moonlighting policies for all inpatient teaching settings.

We found compelling the comments regarding the benefits of the virtual presence and primary care exception policies in rural settings. Accordingly, we believe that permitting the teaching physician to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural training settings, and allowing PFS payment for additional primary care services furnished by residents without the physical presence of a teaching physician in rural areas could increase access to Medicare-covered services by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.<sup>18</sup> Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas.<sup>19</sup> Further, these policies could provide the benefit of additional training opportunities for residents in rural settings, which have historically been in limited supply.<sup>20</sup> As such, the need to improve rural access to care for patients and training for residents overshadows our aforementioned concerns about the teaching physician's ability to render sufficient personal and identifiable physicians' services through virtual presence, or to maintain sufficient personal involvement in all of the care

to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. Accordingly, we believe it would be appropriate to continue these policies in rural settings after the conclusion of the PHE for COVID-19. These policies not only further our goal to increase beneficiary access to Medicare-covered services, they also facilitate needed training opportunities is similar to the rationale for the existing primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policies we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings. Therefore, we are finalizing our virtual presence and primary care exception policies for residency training sites that are located outside of an OMB-defined MSA. In addition, in order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying existing documentation requirements to specify that the patient's medical record must clearly reflect how and when the teaching physician was present during the key portion of the service, in accordance with our regulations.

For our resident moonlighting policies, we believe that complete documentation in the medical record would guard against the risk of potential duplicative payment with the IPPS. Consequently, we are clarifying that, regardless of whether the resident's services are performed in the outpatient department, emergency department or inpatient setting of a hospital in which they have their training program, the patient's medical record must clearly reflect that the resident furnished identifiable physician services that meet the conditions of payment of physician services to beneficiaries in providers in § 415.102(a), that the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and that the services are not

performed as part of the approved GME program.

For the virtual presence, primary care exception and resident moonlighting policies, while we do not anticipate any program integrity concerns, we agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding these flexibilities to include non-rural settings to terminating these flexibilities in all settings. Specifically, we anticipate considering to what degree the permanent establishment of these policies increased patient access to Medicare-covered services and provided additional training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data, or another assessment mechanism, to further study the impacts of these policies to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

## 2. Supervision of Diagnostic Tests by Certain NPPs

In response to E.O. 13890 discussed above, we sought assistance from stakeholders in identifying Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. In response to our request for feedback discussed above, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise the performance of diagnostic tests because they are currently authorized to do so under their state scope of practice rules in many states. In the May 8th COVID-19 IFC (85 FR 27550 through 27629), we established on an interim basis during the PHE for COVID-19, a policy to permit these and certain other NPPs to supervise diagnostic tests. In the CY 2021 PFS proposed rule, we proposed to make those changes permanent by making modifications to the regulations at § 410.32. We noted that we planned to address comments we received on the proposals from the CY 2021 PFS proposed rule and comments received on the May 8th COVID-19 IFC (85 FR 27550 through 27629) simultaneously in this final rule.

Prior to the PHE for COVID-19, under § 410.32(a)(2), physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who are treating

<sup>18</sup> A Guide for Rural Health Care Collaboration and Coordination: <https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf>.

<sup>19</sup> CMS Rural Health Strategy. <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf>.

<sup>20</sup> HHS awards \$20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: <https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html>.

a beneficiary for a specific medical problem may order diagnostic tests when they use the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests. The regulation at § 410.32(b)(1) provided as a basic general rule that all diagnostic tests paid under the PFS must be furnished under an appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2) then provided for certain exceptions to which this basic rule did not apply. For instance, under § 410.32(b)(2)(v), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by an NP or CNS authorized under applicable state law to furnish the test. (We noted that, as for all services furnished by a NP or CNS, they would have to be furnished working in collaboration with a physician as provided in regulations at §§ 410.75 and 410.76, respectively). Similarly, under the regulation at § 410.32(b)(2)(vii), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by a CNM authorized under applicable state law to furnish the test. This exception is in place because the Medicare statute does not include any physician supervision requirement for CNM services. Thus, while NPs, CNSs, PAs, and CNMs were permitted to furnish diagnostic tests to the extent they were authorized under state law and their scope of practice to do so, the regulations at § 410.32 did not address whether these practitioners could supervise others who furnished diagnostic tests.

In light of stakeholder feedback to CMS on identifying additional Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license, effective January 1, 2021, we proposed to amend the basic rule under the regulation at § 410.32(b)(1) to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or "incident to" their own professional

services, to the extent authorized under state law and scope of practice.

We proposed to amend the regulation at § 410.32(b)(2)(iii)(B) on a permanent basis to specify that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and CPs who are currently authorized to supervise these tests. We also proposed to amend on a permanent basis, the regulation at § 410.32 to add paragraph (b)(2)(ix) to specify that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians as defined under § 410.74 would continue to apply. We also proposed to make permanent the removal of the parenthetical, previously made as part of the May 8th COVID-19 IFC (85 FR 27550 through 27629), at § 410.32(b)(3) that required a general level of physician supervision for diagnostic tests performed by a PA.

We received public comments on whether the policies we adopted on an interim basis during the PHE for COVID-19 under § 410.32 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

*Comment:* We received many comments expressing appreciation for the flexibilities that we put in place for purposes of the PHE for COVID-19, allowing NPPs to supervise the performance of diagnostic tests and treat patients at the top of their scope of practice. Additionally, they encouraged CMS to make this flexibility permanent, beyond the COVID-19 pandemic.

*Response:* We appreciate the feedback from these commenters and plan to finalize these provisions as proposed, with modifications described below.

*Comment:* We received a comment that certified registered nurse anesthetists (CRNAs) should be listed among the delineated NPPs, explaining the value of their services within the health care system. The commenter noted that in the CY 2013 PFS final rule (77 FR 69006), CMS indicated Medicare coverage of CRNA services within their state scope of practice. The commenter stated that CRNAs have continuously practiced autonomously, and provide every aspect of anesthesia delivery as well as acute and chronic pain management services.

*Response:* We appreciate the information provided and are adding

CRNAs to the previously enumerated list of NPPs.

*Comment:* Some commenters opposed our proposed change to allow NPPs to supervise the performance of psychological and neuropsychological tests. These commenters provided information indicating that these tests are not within the scope of practice of the proposed NPPs, and require special training only available to psychologists and physicians.

*Response:* We appreciate the information provided by these commenters stating that the specified NPPs are not qualified or authorized by their scope of practice and State law to supervise the performance of this specific category of diagnostic tests. As directed under the E.O. to allow NPPs to practice at the top of their license, our intent regarding this supervision flexibility is to allow NPPs with separate benefit categories under Medicare law to supervise the performance of diagnostic tests, regardless of the specific category of diagnostic tests, only to the extent their scope of practice and State laws authorize them to do so. Accordingly, we believe that the scope of practice and State laws for the State in which the specified NPPs furnish diagnostic psychological and neuropsychological tests will determine whether these NPPs are qualified to supervise the performance of diagnostic psychological and neuropsychological tests in addition to physicians and clinical psychologists who are already authorized to supervise such tests.

*Comment:* Some commenters expressed concern about the ability of NPPs to supervise diagnostic tests beyond the PHE for COVID-19. They opined that such supervision should not extend beyond the PHE for COVID-19. These commenters expressed that while NPPs are critical team members, it is vital to maintain physician-led teams for quality and cost of care. They cited information indicating that NPPs order more tests and prescribe opioids more than physicians, that patients prefer physicians, and that increasing the supply of NPPs does not increase access to care.

*Response:* We appreciate the commenters' feedback; however, we did not find sufficient evidence to support altering our proposal. Accordingly, we are finalizing our policy as proposed on a permanent basis and amending regulations text at § 410.32(b) to include CRNAs in the group of specified NPPs with a separately enumerated Medicare benefit category to who are allowed to supervise the performance of diagnostic tests, as permitted within their scope of

practice and State law for the State in which the test is furnished.

### 3. Pharmacists Providing Services Incident to Physicians' Services

Stakeholders have asked us to clarify that pharmacists can provide services incident to the professional services of a physician or other NPP just as other clinical staff may do. These stakeholders have asked us, in particular, about pharmacists who provide medication management services. Medication management is covered under both Medicare Part B and Part D. We are reiterating the clarification we provided in the May 8th COVID-19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.

We noted that when a pharmacist provides services that are paid under the Part D benefit, the services are not also reportable or paid for under Part B. In addition to circumstances where medication management is offered as part of the Part D benefit, Part B payment is also not available for services included in the Medicare Part D dispensing fees, such as a pharmacist's time in checking the computer for information about an individual's coverage, measurement or mixing of the covered Part D drug, filling the container, physically providing or delivering the completed prescription to the Part D enrollee. Similarly, performing required quality assurance activities consistent with § 423.153(c)(2), such as screening for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, potential over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse are considered part of dispensing fees under Part D and are not separately reportable services under Part B. Additionally, services and supplies paid under the incident to benefit must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness (§ 410.26). We also

noted that our manual provisions specify that "incident to" services must be of a type that are medically appropriate to provide in the office setting; and that where a physician supervises auxiliary personnel to assist him or her in rendering services to patients and includes the charges for their services in his or her own bills, the services of such personnel are considered incident to the physicians' service if there is a physicians' service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician (section 60.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100-02) available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>).

Although it is fully consistent with current CMS policy for pharmacists to provide services incident to the services of the billing physician or NPP, we believe this clarification may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training, licensure and scope of practice. It may free up the time of physicians and NPPs for other work and increase access to medication management services, for individuals with chronic conditions and other conditions. As an example, we found that this clarification was helpful in recently addressing in the May 8th COVID-19 IFC (85 FR 27550 through 27629), the ability of pharmacies to enroll as laboratories and work with physicians in the assessment of clinical information, specimen collection and reporting results of COVID-19 clinical diagnostic laboratory tests.

We received a few public comments on this clarification made in our IFC and proposed rule. The following is a summary of the comments we received and our responses.

*Comment:* We received several comments asking us to allow pharmacists to directly bill office/outpatient E/M visit codes (CPT codes 99202-99215), or if this is not possible, allow physicians to bill these codes for time spent by pharmacists providing services incident to a physician's service. One commenter questioned why we referred to pharmacists as auxiliary staff or auxiliary personnel, and whether the AMA CPT Editorial Panel would agree with this classification.

*Response:* As mentioned above, the Medicare Part B benefit category of services furnished "incident to" the professional services of a physician, describe services furnished by the staff

(or contracted staff) of a physician under his or her supervision. Specifically, section 1861(s)(2)(A) of the Act describes, services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." Our regulation that implements section 1861(s)(2)(A) of the Act similarly describes these services in § 410.26(b) where we specify, among other things, that "incident to" services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness. In the regulation at § 410.26(a), we have long used the term "auxiliary personnel" to describe the individuals who may provide services incident to the professional services of a physician or practitioner who is authorized by law to bill Medicare for their services. The regulation defines the term as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets other stated rules, including licensure rules imposed by the State in which the services are being furnished. This Medicare Part B framework applies to any individual working with the billing physician or other practitioner to provide services on an "incident to" basis, for example, a physician assistant, medical assistant, nurse, pharmacist, administrative assistant or others, whether they have a clinical role or not. The Medicare term "auxiliary personnel" could include staff that have clinical roles and staff that do not.

The CPT codebook that delineates a common system of codes for use by all payers, describes individuals who perform or report a given service using different terms, "physician or qualified health care professional" (QHP) and "clinical staff." The CPT codebook defines these terms as follows, "A 'physician or other qualified health care professional' as an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that

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## Title 42 – Public Health

### Chapter IV – Centers for Medicare & Medicaid Services, Department of Health and Human Services

#### Subchapter B – Medicare Program

#### Part 410 – Supplementary Medical Insurance (SMI) Benefits

#### Subpart B – Medical and Other Health Services

**Authority:** 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

**Source:** 51 FR 41339, Nov. 14, 1986, unless otherwise noted.

**Editorial Note:** Nomenclature changes to part 410 appear at 62 FR 46037, Aug. 29, 1997.

#### § 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

- (a) **Ordering diagnostic tests.** Except as otherwise provided in this section, all diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) of this chapter).
  - (1) **Mammography exception.** A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.
  - (2) **Application to nonphysician practitioners.** Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.
  - (3) **Public Health Emergency exceptions.** During the Public Health Emergency for COVID–19, as defined in § 400.200 of this chapter, the order of a physician or other applicable practitioner is not required for one otherwise covered diagnostic laboratory test for COVID–19 and for one otherwise covered diagnostic laboratory test each for influenza virus or similar respiratory condition needed to obtain a final COVID–19 diagnosis when performed in conjunction with COVID–19 diagnostic laboratory test in order to rule-out influenza virus or related diagnosis. Subsequent otherwise covered COVID–19 and related tests described in the previous sentence are reasonable and necessary when ordered by a physician or nonphysician practitioner in accordance with this paragraph (a), or when ordered by a pharmacist or other healthcare professional who is authorized under applicable state law to order diagnostic laboratory tests. FDA-authorized COVID–19 serology tests are included as covered tests subject to the same order requirements during the Public Health Emergency for COVID–19, as

defined in § 400.20 of this chapter, as they are reasonable and necessary under section 1862(a)(1)(A) of the Act for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected prior COVID-19 infection.

- (4) **Application to audiologists.** Except as otherwise provided in this paragraph, audiologists may personally furnish diagnostic audiology tests for a patient once per patient per 12-month period without an order from the physician or nonphysician practitioner treating the patient. Such diagnostic audiology tests can be for non-acute hearing conditions, but may not include audiology services that are related to disequilibrium, or hearing aids, or examinations for the purpose of prescribing, fitting, or changing hearing aids that are outlined at § 411.15(d). Audiology services furnished without an order from the treating physician or practitioner are billed using a modifier CMS designates for this purpose.

(b) **Diagnostic x-ray and other diagnostic tests –**

- (1) **Basic rule.** Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).
- (2) **Exceptions.** The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:
- (i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.
  - (ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(l)(3) of the Act.
  - (iii) Diagnostic psychological and neuropsychological testing services when—
    - (A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or
    - (B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.
  - (iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.
  - (v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

- (vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.
- (vii) Diagnostic tests performed by a certified nurse-midwife authorized to perform the tests under applicable State laws.
- (viii) During the COVID-19 Public Health Emergency as defined in § 400.200 of this chapter, diagnostic tests performed by a physician assistant authorized to perform the tests under applicable State law.
- (ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(3) **Levels of supervision.** Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraph (b)(3)(ii) or (iii) of this section, respectively. When direct or personal supervision is required, supervision at the specified level is required throughout the performance of the test.

- (i) **General supervision** means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
- (ii) **Direct supervision** in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or, December 31, 2021, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).
- (iii) **Personal supervision** means a physician must be in attendance in the room during the performance of the procedure.

(4) **Supervision requirement for RRA or RPA.** Diagnostic tests that are performed by a registered radiologist assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists or a radiology practitioner assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants, and that would otherwise require a personal level of supervision as specified in paragraph (b)(3) of this section, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

(c) **Portable x-ray services.** Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

- (1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.
- (2) These services are ordered by a physician as provided in paragraph (a) or by a nonphysician practitioner as provided in paragraph (a)(2) of this section.

- (3) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.
- (4) The procedures are limited to—
  - (i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;
  - (ii) Chest or abdominal films that do not involve the use of contrast media; and
  - (iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.

(d) **Diagnostic laboratory tests** —

- (1) **Who may furnish services.** Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:
  - (i) A participating hospital or participating RPCH.
  - (ii) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.
  - (iii) The office of the patient's attending or consulting physician if that physician is a doctor of medicine, osteopathy, podiatric medicine, dental surgery, or dental medicine.
  - (iv) An RHC.
  - (v) A laboratory, if it meets the applicable requirements for laboratories of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.
  - (vi) An FQHC.
  - (vii) An SNF to its resident under § 411.15(p) of this chapter, either directly (in accordance with § 483.75(k)(1)(i) of this chapter) or under an arrangement (as defined in § 409.3 of this chapter) with another entity described in this paragraph.
- (2) **Documentation and recordkeeping requirements** —
  - (i) **Ordering the service.** Except for tests described in paragraph (a)(3) of this section, the physician (or qualified nonphysician practitioner, as defined in paragraph (a)(2) of this section), who orders the service must maintain documentation of medical necessity in the beneficiary's medical record.
  - (ii) **Submitting the claim.** Except for tests described in paragraph (a)(3) of this section, the entity submitting the claim must maintain the following documentation:
    - (A) The documentation that it receives from the ordering physician or nonphysician practitioner.
    - (B) The documentation that the information that it submitted with the claim accurately reflects the information it received from the ordering physician or nonphysician practitioner.

- (iii) **Requesting additional information.** The entity submitting the claim may request additional diagnostic and other medical information to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(3) **Claims review.**

- (i) **Documentation requirements.** Except for tests described in paragraph (a)(3) introductory text, upon request by CMS, the entity submitting the claim must provide the following information:

- (A) Documentation of the order for the service billed (including information sufficient to enable CMS to identify and contact the ordering physician or nonphysician practitioner).
- (B) Documentation showing accurate processing of the order and submission of the claim.
- (C) Diagnostic or other medical information supplied to the laboratory by the ordering physician or nonphysician practitioner, including any ICD-9-CM code or narrative description supplied.

- (ii) **Services that are not reasonable and necessary.** If the documentation provided under paragraph (d)(3)(i) of this section does not demonstrate that the service is reasonable and necessary, CMS takes the following actions:

- (A) Provides the ordering physician or nonphysician practitioner information sufficient to identify the claim being reviewed.
- (B) Requests from the ordering physician or nonphysician practitioner those parts of a beneficiary's medical record that are relevant to the specific claim(s) being reviewed.
- (C) If the ordering physician or nonphysician practitioner does not supply the documentation requested, informs the entity submitting the claim(s) that the documentation has not been supplied and denies the claim.

- (iii) **Medical necessity.** The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) **Automatic denial and manual review.**

- (i) **General rule.** Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

- (ii) **Exceptions.** CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

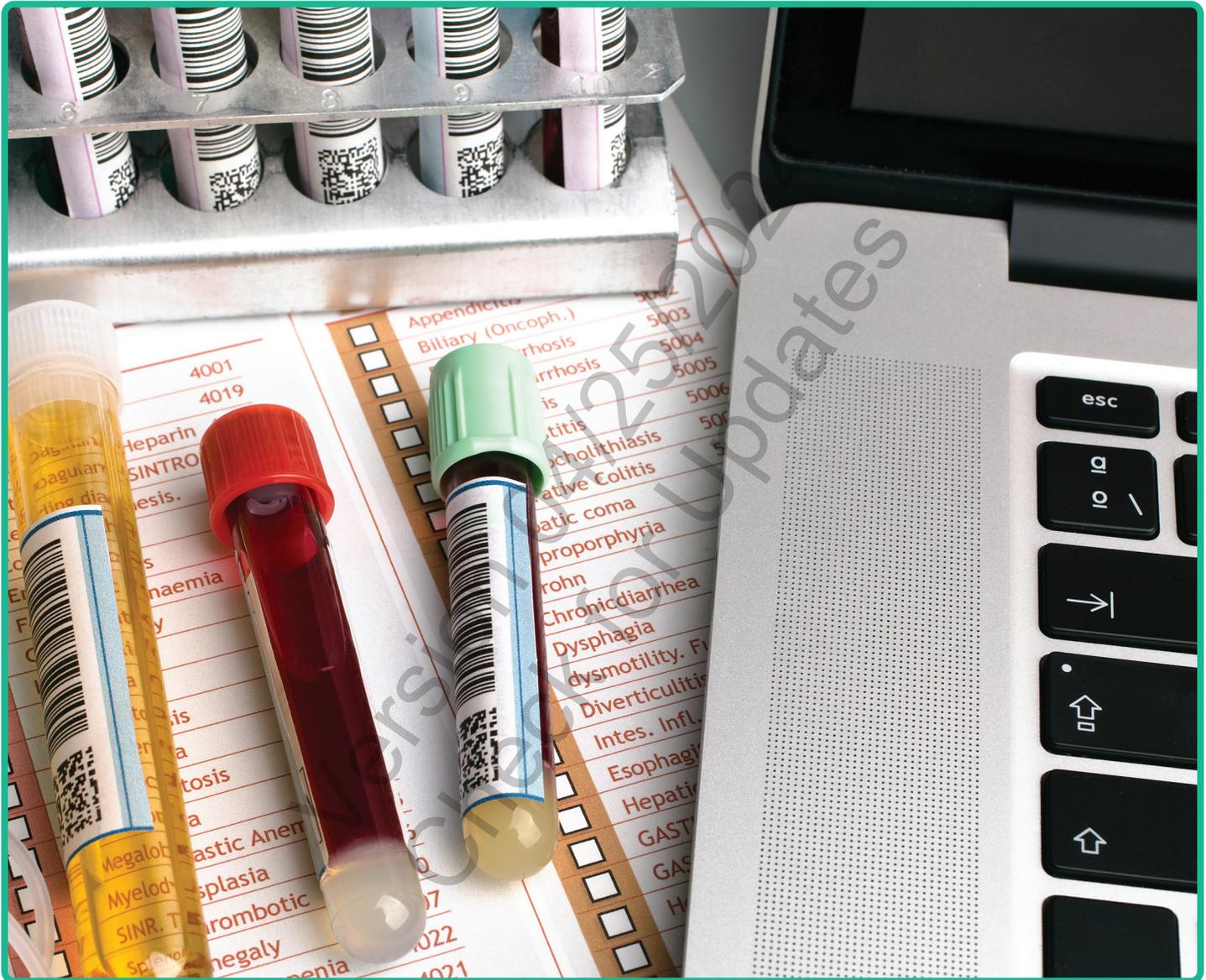
- (e) **Diagnostic laboratory tests furnished in hospitals and CAHs.** The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020; 85 FR 85026, Dec. 28, 2020; 87 FR 70223, Nov. 18, 2022]

Version 04/25/2024  
Check for Updates



### CLIA Program & Medicare Lab Services



### What's Changed?

Note: No substantive content updates.

The COVID-19 public health emergency (PHE) ended on May 11, 2023. View [Infectious diseases](#) for a list of waivers and flexibilities that were in place during the PHE.

The Clinical Laboratory Improvement Amendments (CLIA) Program regulates labs testing human specimens and ensures they provide accurate, reliable, and timely patient test results no matter where the test is done. CMS oversees all lab testing (except some research) done on humans in the U.S. through CLIA.

### CLIA Research

CLIA regulates research testing for returned patient-specific results. CLIA doesn't apply when a statistical research center keeps patient-specific test results for possible use by investigators, and the entity doesn't report patient-specific results.

According to [42 CFR 493.2](#), CLIA applies to all labs examining "materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."

CLIA applies to all entities providing clinical lab services and requires these labs to meet applicable federal requirements. CLIA requires these labs to have a current CLIA certificate, including those labs that don't file Medicare test claims. CLIA requirements also apply to labs in physician offices.

### CLIA Agency Administration Responsibilities

Federal Agency	Responsibilities
<a href="#">CMS</a>	<ul style="list-style-type: none"> <li>• Approves and reapproves private accreditation organizations doing inspections</li> <li>• Approves state exemptions</li> <li>• Collects user fees</li> <li>• Inspects and enforces regulatory compliance</li> <li>• Issues lab certificates</li> <li>• Monitors lab proficiency testing (PT) performance and approves PT programs</li> <li>• Develops, implements, and publishes CLIA rules and regulations</li> </ul>
<a href="#">FDA</a>	<ul style="list-style-type: none"> <li>• Categorizes tests based on complexity</li> <li>• Reviews in vitro diagnostic (IVD) applications for marketing devices</li> <li>• Develops CLIA complexity categorization rules and guidance</li> </ul>

**CLIA Agency Administration Responsibilities (cont.)**

Federal Agency	Responsibilities
<a href="#">CDC</a>	<ul style="list-style-type: none"> <li>• Performs lab quality improvement studies</li> <li>• Develops and distributes professional information and educational resources</li> <li>• Develops technical standards and lab practice guidelines, including cytology guidelines</li> <li>• Manages the <a href="#">Clinical Laboratory Improvement Advisory Committee</a> (CLIAC)</li> <li>• Monitors PT practices</li> <li>• Provides analysis, research, and technical help</li> </ul>

Fees from regulated facilities cover all CLIA Program administration costs, including certificates and surveys.

**Getting CLIA Certification**

To get CLIA certification, labs must:

- Complete the [Clinical Laboratory Improvement Amendments \(CLIA\) Application for Certification Form \(CMS-116\)](#) and mail it to their [CLIA state agency](#). For help with the application, see the [Quick Start Guide](#).
- Pay applicable [certification-type fees](#). Annual testing volume and scope determine moderate and high complexity labs' additional fees.
- Be surveyed, if applicable.
- Meet CLIA certification requirements.

**International Labs**

If your lab is outside the U.S. (and its territories) and seeking CLIA certification, contact [CLIA-IOIntake@cms.hhs.gov](mailto:CLIA-IOIntake@cms.hhs.gov) before completing Form CMS-116.

You can find the certification application at the [How to Apply for a CLIA Certificate, Including International Laboratories](#) webpage. Contact your state agency for help with enrolling.

Include your unique CLIA number on all lab services claims. This 10-character alpha-numeric code identifies and tracks your lab's history. Use this number when contacting your state agency or us.

## Lab Certificates

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The CLIA Program grants 5 types of lab certificates.

### Certificate of Waiver

The Certificate of Waiver (CoW) allows labs to do tests the FDA categorizes as waived tests, including:

- Certain glucose and cholesterol testing methods
- Fecal occult blood tests
- Pregnancy tests
- Some urine tests

Labs that do **only** waived testing must:

- Enroll in the CLIA Program
- Pay applicable certificate fees every 2 years
- Follow manufacturer's test instructions

Labs with a CoW don't get surveyed every 2 years. Lab surveys happen if:

- There's a complaint
- The testing is beyond the certificate's scope
- There's risk of harm from inaccurate testing
- There's a need to collect waived tests information

The [Categorization of Tests](#) webpage has more CLIA-waived tests information.

#### What are Waived Tests?

The FDA [waives](#) tests it categorizes as simple, low-risk tests for an incorrect result or with no reasonable risk of harm. Labs with a different certificate type can do waived tests without getting a separate CoW.

## Provider-Performed Microscopy Procedures Certificate

The Provider-Performed Microscopy Procedures (PPMP) certificate is a subset of moderate complexity tests and a unique lab classification and certification where a physician, mid-level practitioner, or dentist provides **only** certain microscopy procedures and waived tests during a patient's visit.

A PPMP is a moderate complexity test using a bright-field or phase-contrast microscope (for example, urine sediment exams or potassium hydroxide (KOH) preparations).

A physician, mid-level practitioner (under supervision if state law requires), or dentist must personally perform the specimen procedures during the visit.

Labs with a PPMP certificate don't get surveyed every 2 years. Lab surveys happen if:

- There's a complaint
- The testing is beyond the certificate's scope
- There's risk of harm from inaccurate testing
- There's a need to collect [PPMP](#) information

## Certificate of Registration

Labs applying for a Certificate of Compliance (CoC), or Certificate of Accreditation (CoA), first get a Certificate of Registration (CoR). A CoR is temporary and allows a lab to perform moderate and high complexity tests until it gets surveyed to verify it meets CLIA regulations.

If a lab is applying for a CoA or CoC, a CoR shows registration with the CLIA Program and allows it to operate until initial compliance is assessed. A CoR is valid only for 2 years.

## Certificate of Compliance

A lab gets a CoC after an on-site survey finds it meets all applicable CLIA regulations. Surveys happen every 2 years at CoC labs doing moderate and high complexity testing. The surveys:

- Help labs improve patient care through education and emphasize requirements directly impacting its quality test performance
- Determine labs' regulatory compliance

The surveyor decides whether labs meet CLIA regulations by:

- Interviewing personnel
- Observing current practices
- Reviewing relevant records

## Certificate of Accreditation

Labs that do moderate and high complexity tests get CoAs when they meet the standards of a private non-profit accreditation organization (AO) approved by CMS:

- To get approved, a non-profit AO's standards must meet or exceed CLIA regulatory requirements
- Every 6 years or sooner, each organization reapplies for continued authority to ensure its standards meet or exceed CLIA's requirements
- An AO inspects labs once every 2 years
- We do a [validation survey](#) on a representative sample of accredited labs or may do a complaint survey in response to substantial non-compliance allegations
- We complete annual validation surveys of each AO's performance

The [Accreditation Organizations/Exempt States](#) webpage lists approved AOs.

## CLIA Proficiency Testing

Labs doing moderate and high complexity testing must participate in PT for certain tests. PT offers each lab doing non-waived tests a way to measure performance and verify accuracy and reliability.

A CMS-approved PT program sends labs a set of PT samples 3 times each year. Labs test the PT samples the same way as patient specimens and report the results to the PT program. The PT program grades the results and returns the scores to labs, so they know how accurately they tested. CMS reappraises PT programs annually. The [Proficiency Testing Programs](#) webpage has more information.

### Did You Know?

Even if it's common practice for patient specimens, don't refer PT samples to another lab for analysis.

## Test Categorization

The FDA categorizes each test based on complexity. Use the [CLIA database](#) to search by test system name, analyte name, complexity, specialty, and effective date.

The FDA categorizes tests into these complexity levels:

- Waived complexity
- Moderate complexity, including the PPMP subcategory
- High complexity

When categorizing a test, the FDA considers:

- Test knowledge needed
- Test training and experience needed
- Reagents and materials preparation
- Operational steps characteristics
- Calibration, quality control, and PT materials
- Test system troubleshooting and equipment maintenance
- Interpretation and judgment needed

CLIA quality standards requirements, personnel qualifications, and responsibilities are stricter for more complicated tests.

## Medicare Lab Services

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We cover lab services and other diagnostic tests, including materials and technician services, when:

- A treating physician or qualified non-physician practitioner orders or refers the services or tests
- Services are medically reasonable and necessary and meet all CLIA regulations

The [Clinical Labs Center](#) webpage has more lab services payment and other diagnostic tests information.

## Resources

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- [CDC CLIA](#)
- [CLIA Brochures](#)
- [CLIA FAQs](#)
- [CLIA Regulations and Federal Register Documents](#)
- [Clinical Laboratory Fee Schedule](#)
- [Medicare Claims Processing Manual](#)
- [National Coverage Determinations \(NCDs\) for Lab Tests](#)

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## New Waived Tests

Related CR Release Date: March 7, 2024

MLN Matters Number: MM13546

Effective Date: April 1, 2024

Related Change Request (CR) Number: [CR 13546](#)

Implementation Date: April 1, 2024

Related CR Transmittal Number: R12534CP

### Affected Providers

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- Hospitals
- Physicians
- Suppliers

### Action Needed

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Make sure your billing staff knows about:



- Clinical Laboratory Improvement Amendments (CLIA) requirements
- New CLIA-waived tests approved by the FDA
- Use of modifier QW for CLIA-waived tests

### Background

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CLIA regulations require a facility to be appropriately certified for each test they do. CMS edits laboratory claims at the CLIA certificate level to make sure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate.

Listed below are the latest tests approved by the FDA as waived tests under CLIA. The HCPCS codes for the following new tests must have the modifier QW to be recognized as a waived test.



The HCPCS codes, effective date, and description for the latest tests the FDA approved as waived tests under CLIA are:

- 0352UQW, October 19, 2023, Cepheid GeneXpert Xpress System {Xpert Xpress MVP} Under Proprietary Laboratory Analyses
- 82274QW, G0328QW, November 13, 2023, Rodimedi & Associates Inc. RedTunica iFOB One Step Rapid Test
- 80305QW, November 16, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methamphetamine (MET/mAMP) Urine Test Panel
- 80305QW, November 17, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methadone (MTD) Urine Test Panel

- 80305QW, November 30, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methylenedioxyamphetamine (MDMA) Urine Test Panel
- 82274QW, G0328QW, November 30, 2023, Diacarta INC. iCOLON iFOB TEST immunochemical Fecal Occult Blood Test (See analysis tab)
- 82274QW, G0328QW, November 30, 2023, DiaCarta Inc. iCOLON iFOB TEST immunochemical Fecal Occult Blood Test
- 82274QW, G0328QW, December 01, 2023, DiaCarta Inc iCOLON iFOB TEST immunochemical Fecal Occult Blood Test
- 80305QW, December 22, 2023, McKesson Medical-Surgical Inc. McKesson Consult Fentanyl Urine Test Cassette
- 80305QW, December 05, 2023, American Screening Corp Discover Fentanyl Rapid Test Cassette
- 80305QW, December 05, 2023, Verify Diagnostics Inc. VeriCheck Drug Test Cup (Urine)
- 80305QW, December 06 ,2023, CLIAWaived Inc. Test Yourself At Home Home Rapid Test Cup (Urine)
- 80305QW, December 06, 2023, CLIAwaived Inc. Rapid Drug Test Device "RDTD" for Fentanyl in Urine
- 80305QW, December 06, 2023, Instant Technologies Inc. iCassette Fentanyl Urine Test Cassette
- 80305QW, December 06, 2023, Healgen Scientific LLC Healgen Drug of Abuse Urine Quick Split Cup
- 80305QW, December 07, 2023, Wondfo USA Co. Ltd. SAFElife T-Dip Methamphetamine (MET500/mAMP500) Urine Test Panel
- 80305QW, December 14, 2023, Wondfo USA Co. Ltd SAFElife Cannabinoids (THC) Urine Test
- 87400QW, December 14, 2023, Becton Dickinson and Company BD Veritor Plus Analyzer {BD Veritor System for Rapid Detection of Flu A+B CLIA-Waived Kit} (For use with nasal swabs only)
- 80305QW, December 15, 2023, Hangzhou AllTest Biotech Co. Ltd. AllTest Multi-Drug Rapid Test Panel
- 80305QW, December 15, 2023, Hangzhou AllTest Biotech Co. Ltd. AllTest Multi-Drug Rapid Test Cup
- 80305QW, December 18, 2023, Wondfo USA Co Ltd. SAFElife T-Dip Propoxyphene (PPX) Urine Test Panel
- 80305QW, December 18, 2023, Preferred Med Supply #1 Best Multi-Panel Drug Test Cup
- 80305QW, December 22, 2023, McKesson Medical-Surgical Inc. McKesson Consult Fentanyl Urine Test Cassette
- 80305QW, December 22, 2023, Guangzhou Decheng Biotechnology Co. Ltd. Docheck Multi-Drug Urine Test Cup
- 80305QW, December 27, 2023, Medical Distribution Group Inc. Identify Diagnostics Fentanyl Urine Cassette

Find FDA approval information about these tests and their use by:

- Using the [FDA search feature](#)
- Referring to the FDA Review Decision Summary documentation about the tests

MACs won't search their files to either take back payment or retroactively pay claims affected by CR 13546. They'll adjust claims you bring to their attention.

## More Information

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We issued CR 13546 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

## Document History

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Date of Change	Description
March 7, 2024	Initial article released.

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CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 12415	Date: December 19, 2023
	Change Request 13455

**Transmittal 12381 issued November 24, 2023, is being rescinded and replaced by Transmittal 12415, dated December 19, 2023, to update the Background section to revise the QW code information among the 80 tests and to add 24 new waived tests with their corresponding QW codes approved by the FDA as of December 5, 2023. In addition, the attachment and CR summary has been updated. All other information remains the same.**

**SUBJECT: New Waived Tests**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to inform contractors of new Clinical Laboratory Improvement Amendments of 1988 (CLIA) waived tests approved by the Food and Drug Administration. Since these tests are marketed immediately after approval, the CMS must notify its contractors of the new tests so that the contractors can accurately process claims. There are 104 newly added waived complexity tests. This Recurring Update Notification applies to Chapter 16, section 70.8 of the Internet Only Manual (IOM).

**EFFECTIVE DATE: January 1, 2024**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: January 2, 2024**

**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**

Version 04/25/2024  
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## Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 12415	Date: December 19, 2023	Change Request: 13455
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**Transmittal 12381 issued November 24, 2023, is being rescinded and replaced by Transmittal 12415, dated December 19, 2023, to update the Background section to revise the QW code information among the 80 tests and to add 24 new waived tests with their corresponding QW codes approved by the FDA as of December 5, 2023. In addition, the attachment and CR summary has been updated. All other information remains the same.**

**SUBJECT: New Waived Tests**

**EFFECTIVE DATE: January 1, 2024**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: January 2, 2024**

### I. GENERAL INFORMATION

**A. Background:** The Clinical Laboratory Improvement Amendments of 1988 (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 a CLIA certificate of waiver, laboratory claims are currently edited at the CLIA certificate level.

Listed below are the latest tests approved by the Food and Drug Administration (FDA) as waived tests under CLIA. The Healthcare Common Procedure Coding System (HCPCS) 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., HCPCS 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 HCPCS code, effective date, and description for the latest tests approved by the FDA as waived tests under CLIA are the following:

#### CODE EFFECTIVE DATE TEST/MANUFACTURER

- 87631QW May 5, 2023 Biofire Diagnostics SPOTFIRE Respiratory Panel Mini
- 80305QW May 15, 2023 American Screening Corporation Discover Plus Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation G-Card Drug Test Dip Card
- 80305QW May 15, 2023 American Screening Corporation G-Cup Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation Onescreen Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation Precision DX Drug Test Dip Card
- 80305QW May 15, 2023 American Screening Corporation Precision DX Multi-Panel Drug Test Cup
- 80305QW May 15, 2023 American Screening Corporation Precision Plus Drug Test Dip Card
- 80305QW May 15, 2023 American Screening Corporation Precision Plus Multi-Panel Drug Test Cup
- 80305QW May 19, 2023 Carethetic Group Corporation Carethetic Marijuana test kit (THC urine test)
- 80305QW May 19, 2023 Carethetic Group Corporation Carethetic Multi Drug Test Cup
- 80305QW May 19, 2023 Carethetic Group Corporation Carethetic Multi Drug Test Panel
- 80305QW May 25, 2023 Instant Technologies Inc. iSCREEN<sup>®</sup> URINE TEST DRUG SCREEN CLICK CUP
- 80305QW May 25, 2023 Instant Technologies Inc. iSCREEN<sup>®</sup> URINE TEST DRUG SCREEN FLAT CUP

- 80305QW May 25, 2023 Instant Technologies Inc. iSCREENâ,,ç URINE TEST DRUG SCREENING CLICK CUP
- 80305QW May 25, 2023 Medical Distribution Group Bicycle Health CLIA WAIVED DRUG TEST
- 80305QW May 25, 2023 Neopharma Technologies Sdn. NEOTEST Drug Test Dip Card
- 80305QW May 25, 2023 Neopharma Technologies Sdn. NEOTEST Drug Test Multi Panel Cup (Urine)
- 80305QW May 31, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Cup
- 80305QW May 31, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi-Drug Urine Test Dip Card
- 80305QW June 5, 2023 Wal-Mart Stores Inc. Equate Multi Panel Urine Test Cup
- 87635QW June 20, 2023 Cue Health Inc. Cue Health Monitoring System (For use with Anterior Nasal Swabs)
- 80305QW June 22, 2023 Pregmate LLC ez level MARIJUANA THC DRUG TEST
- 80305QW June 22, 2023 Pregmate LLC ez level DRUG TEST
- 80305QW June 23, 2023 VivaChek Diagnostics Inc. BioSieve Multi-Drug Urine Test Cup
- 80305QW June 26, 2023 Walgreen Co. Walgreens Multi Panel Urine Test Cup
- 87420QW June 29, 2023 Healgen Scientific LLC Rapid Check RSV Antigen Test (Nasopharyngeal swabs)
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Cup
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Cup LC
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card
- 80305QW July 7, 2023 Smartox SMARTEST One Step Multi-Drug Screen Test Dip Card LC
- 80305QW July 10, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW THC Urine Strip Test
- 80305QW July 10, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Cup
- 80305QW July 10, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Multi-Drug Urine Test Dip Card
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine Cassette
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Cocaine DipCard
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana Cassette
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Marijuana DipCard
- 80305QW July 11, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Dip Card (Buprenorphine (BUP))
- 80305QW July 11, 2023 Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M300
- 80305QW July 11, 2023 Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test
- 80305QW July 11, 2023 BTNX Inc. L-Cup Home Rapid Test (Urine)
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine Cassette
- 80305QW July 11, 2023 Safecare Biotech (Hangzhou) Co. Ltd. FIRSTVIEW Urine Test Amphetamine DipCard
- 80305QW July 11, 2023 Azure Biotech Inc. Fastep QuickCup Multi Drug Urine Test M2000
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Dip Card (Oxycodone (OXY))
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Dip Card (Morphine (MOP))
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Dip Card (Methylenedioxyamphetamine (MDMA))
- 80305QW July 17, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Dip Card (Methamphetamine (MET))

- 85610QW July 27, 2023 ARKRAY USA Assure PT Care Prothrombin Time PT/INR Monitoring System Professional Use
- 87631QW July 27, 2023 Roche Molecular cobas Liat System {Cobas SARS-CoV-2 & Influenza A/B}
- 80305QW August 2, 2023 Easy Healthcare Corporation Easy@Home Single Drug Screen Test (Cocaine Urine Test)
- 80305QW August 3, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Dip Card
- 87635QW August 10, 2023 Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)
- 80305QW August 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO THC One Step Marijuana Test Dip Card
- 80305QW August 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Multi Panel Drug Urine Test Cup
- 80305QW August 15, 2023 Smartox SMARTEST Drug of Abuse Urine Test Cup
- 87420QW August 21, 2023 Versea Diagnostics LLC Versea Easy Lab PRO Rapid RSV Test
- 80305QW August 23, 2023 BTNX Inc. Rapid Response Multi-Drug One Step Cup
- 80305QW August 24, 2023 Clarity Diagnostics LLC. Clarity Multi-Drug Urine Test Cup (Urine)
- 80305QW August 24, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Compact Round Cup
- 80305QW August 24, 2023 Instant Technologies Inc. iSCREENâ,,ç Urine Test Dx Drug Screen Round Cup
- 80305QW August 28, 2023 Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit For Cannabis
- 80305QW August 28, 2023 Citest Diagnostics Inc. Citest Multiplex DOA Home Test Cup (Urine)
- 80305QW August 28, 2023 Citest Diagnostics Inc. Citest Multiplex DOA Home Test Panel (Urine)
- 80305QW August 28, 2023 Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Five (5) Drugs
- 80305QW August 28, 2023 Genabio Diagnostics Inc. GenaCheck Rapid Self-Test Kit for Twelve (12) Drugs
- 80305QW September 8, 2023 Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ,,ç Marijuana Test Panel 50
- 80305QW September 8, 2023 Vivachek Biotech (hangzhou) Co. Ltd BioSieveâ,,ç Marijuana Test Strip 50
- 80061QW, 82465QW, 83718QW, 84478QW September 20, 2023 Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)
- 86769QW, 87426QW, 87811QW September 20, 2023 Quidel Sofia 2
- 83986QW September 22, 2023 Genabio Diagnostics Inc. GenaCheck Vaginal Health pH Screening Test
- 83036QW September 27, 2023 Abbott Diagnostics Technologies AS Afinion 2 analyzer {Afinion HbA1c}
- 83036QW September 27, 2023 Abbott Diagnostics Technologies AS AS100 Analyzer {Afinion HbA1c}
- 83036QW September 29, 2023 Siemens Healthcare Diagnostics Inc. DCA Vantage Analyzer {Siemens DCA Systems Hemoglobin A1c Reagent Kit}
- 85018QW October 2, 2023 Sanguina Inc. AnemoCheck Home
- 80305QW October 2, 2023 Docheck USA Inc. Amazewell Multi-Drug Urine Test Cup
- 80305QW October 2, 2023 Wondfo USA Co. Ltd. SAFElife C-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023 Wondfo USA Co. Ltd. SAFElife T-Cup Multi-Drug Urine Test Cup
- 80305QW October 2, 2023 Wondfo USA Co. Ltd. SAFElife T-Dip Multi-Drug Urine Test Panel
- 80305QW October 18, 2023 McKesson Medical-Surgical Inc. McKesson Drugs of Abuse Test 14-Drug Panel with Adulterants
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 81514QW October 19, 2023 Cepheid GeneXpert Xpress System {Xpert Xpress MVP}
- 87420QW October 19, 2023 Clarity Diagnostics LLC Clarity RSV Antigen Test
- 85018QW October 20, 2023 Henry Schein OneStep+ Pro Hb System

- 80305QW October 24, 2023 FSA Store Inc. Caring Mill Amphetamine Tests Strip
- 80305QW October 26, 2023 Wondfo USA Co. Ltd. SAFElife T-Dip Amphetamine (AMP500) Urine Test Panel
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill 14 Multi-Test Cup
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill 14 Multi-Test Panel
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill Multi-Test Cup
- 80305QW October 30, 2023 FSA Store Inc. Caring Mill Multi-Test Panel
- 80305QW October 30, 2023 G128 LLC Mintegrity Multi-Drug Urine Test Cup
- 80305QW October 30, 2023 G128 LLC Mintegrity Multi-Panel Urine Test
- 80305QW November 2, 2023 Sakar International Inc. drugconfirm Multi-Test Cup
- 80305QW November 2, 2023 Sakar International Inc. drugconfirm Multi-Test Panel
- 80305QW November 6, 2023 Hangzhou AllTest Biotech Co. Ltd. AllTest Fentanyl Urine Test Cassette
- 80305QW November 6, 2023 2San LLC. 2SAN Home Drug Test Cup
- 80305QW November 16, 2023 American Screening Corporation Discover Multi-Drug Rapid Test Cup (Urine)
- 80305QW November 16, 2023 Lendas UAB Exploro Highly Sensitive 5-Panel Urine Drug Test
- 80305QW November 16, 2023 VivaChek Biotech (Hangzhou) Co. Ltd. BioSieve Multi-Drug Urine Test Panel
- 86769QW, 87426QW, 87811QW November 17, 2023 ACON Laboratories Inc. Flowflex COVID-19 Antigen Home Test (For use with Anterior Nasal Swabs)
- 80305QW December 1, 2023 Medical Distribution Group Inc. DrugTect Fentanyl Urine Cassette
- 80305QW November 14, 2023 Shanghai Douglas Medical Device Co. Ltd. ACCUBIO Accurate Oral Fluid Drug Test COT

This Recurring Update Notification applies to Chapter 16, Section 70.8 of the IOM.

**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 categorized as waived complexity under CLIA in facilities with a CLIA certificate of waiver, 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	
13455.1	The Medicare contractor shall include the new tests listed above in CLIA-covered code files with the QW modifier.		X							
13455.2	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.		X							
13455.3	Contractors shall not use the explanatory information under		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	the "Use" column in the attachment as the reason for rejecting a claim.									

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13455.4	Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your local information after we release the MLN Connects newsletter. Subscribe to the "MLN Connects" listserv to get MLN content notifications. You don't need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.		X			

**IV. SUPPORTING INFORMATION**

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

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

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

**V. CONTACTS**

**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: 1**

Version 04/25/2024  
Check for Updates

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81002	Dipstick or tablet reagent urinalysis – non-automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81025	Urine pregnancy tests by visual color comparison	Various	Diagnosis of pregnancy
82270 82272 (Contact your Medicare carrier for claims instructions.)	Fecal occult blood	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening)
82962	Blood glucose by glucose monitoring devices cleared by the FDA for home use	Various	Monitoring of blood glucose levels
83026	Hemoglobin by copper sulfate – non-automated	Various	Monitors hemoglobin level in blood
84830	Ovulation tests by visual color comparison for human luteinizing hormone	Various	Detection of ovulation (optimal for conception)
85013	Blood count; spun microhematocrit	Various	Screen for anemia
85651	Erythrocyte sedimentation rate – non-automated	Various	Nonspecific screening test for inflammatory activity, increased for majority of infections, and most cases of carcinoma and leukemia

Version 04/25/2024  
Check for Updates

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80048QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	Measures total calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and blood urea nitrogen (BUN) in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Basic Metabolic Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Basic Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Basic Metabolic Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
80051QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	Measures carbon dioxide, chloride, potassium, and sodium in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Electrolyte Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Electrolyte Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Electrolyte Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	
80053QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	Measures alanine amino transferase, aspartate amino transferase, albumin, total bilirubin, total calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, and BUN in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Comprehensive Metabolic Panel Reagent Disc} (Whole Blood)	Abaxis, Inc.	Measures alanine amino transferase, aspartate amino transferase, albumin, total bilirubin, total calcium, carbon dioxide, chloride, creatinine, glucose, alkaline phosphatase, potassium, total protein, sodium, and BUN in whole blood

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80053QW (cont.)	3. Abaxis Piccolo xpress Chemistry Analyzer (Comprehensive Metabolic Reagent Disc){Whole Blood}	Abaxis, Inc.	
	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Comprehensive Metabolic Panel Reagent Disc} (Whole Blood)		
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW	Cholesterol level, HDL cholesterol level and triglycerides level. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.	Various	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW	1. Infopia USA LipidPro lipid profile and glucose measuring system	Infopia Co., Ltd.	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	2. Alere San Diego Inc. Cholestech LDX {Lipid Profile cassette} (Whole Blood)	Alere San Diego Inc.	
	3. Infopia USA LipidPro Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	
	4. Jant Pharmacal LipidPlus Lipid Profile and Glucose Measuring System	Infopia Co., Ltd.	

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82962, 83718QW, 84478QW (cont.)	5. Jant Pharmacal Corp, LipidPlus Professional Lipid Profile and Glucose Measuring System	Infopia Co., Ltd	Monitoring of blood glucose levels and measures total cholesterol, HDL cholesterol, and triglycerides in whole blood
	6. KPI Healthcare Co., Ltd. CURO L5 Lipid Profile and Glucose Measuring System	Osang Healthcare Co., Ltd.	
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84460QW, 84478QW	Cholestech LDX (Lipid Profile – ALT (GPT)){Whole Blood}	Cholestech Corp.	Measures alanine aminotransferase, total cholesterol, HDL cholesterol, and triglycerides in whole blood
80061QW, 82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84450QW, 84460QW, 84478QW 80069QW	1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and BUN in whole blood
	2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Renal Function Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	
	3. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Renal Function Panel){Whole Blood}	Abaxis, Incorporated	Measures albumin, total calcium, total carbon dioxide, chloride, creatinine, glucose, phosphorus, potassium, sodium and BUN in whole blood

Version 04/25/2024  
Check for Updates

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
80069QW (cont.)	4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Renal Function Panel Reagent Disc} (Whole Blood)	Abaxis, Incorporated	
80178QW	ReliaLAB Inc. InstaRead Lithium System {fingerstick or venipuncture whole blood}	Akers Laboratories, Inc.	Measures lithium blood levels in whole blood
80305QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.)	Drug test(s), presumptive, any number of drug classes; any number of devices or procedures, (e.g., immunoassay) capable of being read by direct optical observation only (e.g., dipsticks, cups, cards, cartridges) categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.	Various	Screening test for the presence/detection of any number of drug classes in urine
81003QW	Dipstick or tablet reagent urinalysis – automated for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections
81003QW, 82044QW, 82570QW	Siemens Clinitek 50 Urine Chemistry Analyzer	Siemens Healthcare Diagnostics Inc.	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; and the semi-quantitative measurement of albumin and creatinine in urine

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
81003QW, 82044QW, 82570QW, 84703QW	1. Siemens Clinitek Status Urine Chemistry Analyzer	Siemens Healthcare Diagnostics	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections; the semi-quantitative measurement of albumin and creatinine in urine; and the diagnosis of pregnancy
	2. Siemens, Clinitek Status+ Analyzer	Siemens Healthcare Diagnostics	
	3. Siemens, Clinitek Status Connect System	Siemens Healthcare Diagnostics	
81007QW	1. Diatech Diagnostics Uriscreen (for OTC use)	Savyon/USA	Detects catalase in urine which is associated with urinary tract infections (UTIs). White blood cells and some bacteria associated with UTIs are positive for catalase.
	2. Jant Pharmacal Corporation Accutest Uriscreen (Bacteriuria)	Savyon Diagnostics Ltd	
81514QW	1.Cepheid GeneXpert Xpress System {Xpert Xpress MVP}*	Cepheid	This test is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis, or trichomoniasis. The test is a qualitative real-time polymerase chain reaction (PCR) assay that amplifies specific DNA targets from the above-mentioned organisms via fluorogenic target-specific hybridization probes that detect and differentiate targeted DNA.
82010QW	1. AmVenturex, Inc., KetoCoach Blood Ketone Monitoring System	Apex BioTechnology Corp.	Measures ketones in whole blood
	2. Apex Biotechnology Corp., KET-1 Blood Ketone Monitoring System	Apex Biotechnology Corp.	
	3. PTS Bioscanner (for OTC use) - for blood ketones	Polymer Technology Systems, Inc.	

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82010QW, 82962	Monitoring of blood glucose levels and measures ketones - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Monitoring of blood glucose levels and measures ketones in whole blood
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma-glutamyl transferase, glucose, total bilirubin, total protein, blood urea nitrogen (BUN) and uric acid in whole blood
82040QW, 82150QW, 82247QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84075QW, 84155 QW, 84450QW, 84460QW, 84520QW, 84550QW	Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 13 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, calcium, creatinine, gamma-glutamyl transferase, glucose, total bilirubin, total protein, urea nitrogen and uric acid in whole blood
82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW	1. Abaxis Piccolo Point of Care Chemistry Analyzer (Liver Panel Plus Reagent Disc){whole blood}	Abaxis, Inc.	Measures alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, gamma-glutamyl transferase, total bilirubin and total protein levels in whole blood
82040QW, 82150QW, 82247QW, 82977QW, 84075QW, 84155QW, 84450QW, 84460QW (cont.)	2. Abaxis Piccolo xpress Chemistry Analyzer {Liver Panel Plus} (Whole Blood)	Abaxis, Inc	

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82040QW, 82310QW, 82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 84520QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 1) {Whole Blood}	Polymedco, Inc.	Measures albumin, total calcium, creatinine, glucose and total protein levels in whole blood
82043QW	HemoCue Albumin 201 System	HemoCue, Inc.	Quantitative measurement of albumin in urine by immunoassay
82044QW, 82570QW	<ol style="list-style-type: none"> <li>1. Acon Laboratories, Inc. Mission U120 Urine Chemistry Test System (Mission Urinalysis Reagent Strips (Microalbumin/Creatinine))</li> <li>2. BTNX, Inc., Rapid Response U120S Urine Analyzer Test System (BTNX, Inc. Rapid Response Urinalysis Reagent Strips (Microalbumin/Creatinine))</li> <li>3. Medline Industries, Inc., Medline 120 Mini Analyzer Test System (Medline Industries, Inc. Medline Urinalysis Reagent Strips)</li> </ol>	<p>ACON Laboratories, Inc.</p> <p>ACON Laboratories, Inc.</p> <p>ACON Laboratories, Inc.</p>	Semi-quantitative measurement of albumin and creatinine in urine
82120QW, 83986QW	<ol style="list-style-type: none"> <li>1. Litmus Concepts FemExam TestCard (from vaginal swab)</li> <li>2. GenaCheck Vaginal Health pH Screening Test*</li> </ol>	<p>Litmus Concepts, Inc.</p> <p>Genabio Diagnostics Inc.</p>	Qualitative test of a vaginal fluid sample for elevated pH (pH greater than or equal to 4.7) and the presence of volatile amines
82247QW, 84075QW, 84155QW, 84450QW, 84460QW	Arkay SPOTCHEM EZ Chemistry Analyzer (Spotchem II Basicpanel 2) {Whole Blood}	Polymedco, Inc.	Measures alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, total bilirubin and urea levels in whole blood
82271QW	<ol style="list-style-type: none"> <li>1. Aerscher Hemaprompt FG</li> <li>2. SmithKline Gastrocult</li> </ol>	<p>Aerscher Diagnostics</p> <p>SmithKline</p>	Rapid screening test to detect the presence of gastric occult blood
82271QW, 83986QW	Beckman Coulter Primary Care Diagnostics Gastrocult®	Beckman Coulter, Inc.	Rapid screening test to detect the presence of gastric occult blood and determine the pH (acid-base balance) of gastric aspirates

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82274QW G0328QW	Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Detection of blood in feces from whatever cause, benign or malignant (colorectal cancer screening) by immunoassay
82374QW, 82435QW, 82550QW, 82565QW, 82947QW, 84132QW, 84295QW, 84520QW	<ol style="list-style-type: none"> <li>1. Abaxis Piccolo Blood Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}</li> <li>2. Abaxis Piccolo Blood Chemistry Analyzer {Piccolo Metlyte 8 Panel Reagent Disc} (Whole Blood)</li> <li>3. Abaxis Piccolo xpress Chemistry Analyzer (Piccolo Metlyte 8 Panel Reagent Disc) {Whole Blood}</li> <li>4. Abaxis Piccolo xpress Chemistry Analyzer {Piccolo Metlyte 8 Panel Reagent Disc} (Whole Blood)</li> </ol>	<p>Abaxis, Inc.</p> <p>Abaxis, Inc.</p> <p>Abaxis, Inc.</p> <p>Abaxis, Inc.</p>	Measures chloride, creatine kinase, creatinine, glucose, potassium, sodium, total carbon dioxide and BUN in whole blood
82465QW (Contact your Medicare carrier for claims instructions.)	Cholesterol level. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Cholesterol monitoring
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW	<ol style="list-style-type: none"> <li>1. Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+Glu test strips)</li> </ol>	Polymer Technology Systems, Inc.	Measures total cholesterol, and glucose in whole blood

This list includes updates from FFS13455

\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
	2. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+Glu test strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW	Cholesterol level, and HDL cholesterol level. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.	Various.	Measures total cholesterol and HDL cholesterol in whole blood
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 82947QW, 82950QW, 82951QW, 82952QW	1. Polymer Technology Systems CardioChek Brand Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	Measures total cholesterol, HDL cholesterol, and glucose in whole blood
	2. Polymer Technology Systems, Inc., CardioChek Home Test System (CardioChek Home Chol+HDL+Glu test strips)	Polymer Technology Systems, Inc.	
	3. Polymer Technology Systems, Inc., CardioChek Plus Test System (PTS Panels Chol+HDL+Glu test strips)	Polymer Technology Systems, Inc.	
	4. Polymer Technology Systems CardioChek PA Analyzer (PTS Panels CHOL+HDL+GLUC Panel Test Strips)	Polymer Technology Systems, Inc.	
82465QW (Contact your Medicare carrier for claims instructions.), 83718QW, 84478QW, 80061QW	ACON Laboratories Inc., Mission Lipid Panel Monitoring System (ACON Laboratories Inc., Mission Lipid Panel Test Cartridges)	ACON Laboratories Inc.	Measures total cholesterol, HDL cholesterol, and triglycerides in whole blood

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\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 80061QW	Cholestech LDX	Cholestech Corp.	Measures total cholesterol, glucose, HDL cholesterol, and triglycerides in whole blood
82465QW (Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83036QW, 84478QW	Wako APOLOWAKO Analyzer (Whole Blood)	Wako Chemicals USA, Inc.	Measures total cholesterol, hemoglobin A1c, glucose, and triglycerides in whole blood
82465QW(Contact your Medicare carrier for claims instructions.), 82947QW, 82950QW, 82951QW, 82952QW, 83718QW, 84478QW, 84450QW, 84460QW	Abaxis Piccolo xpress Chemistry Analyzer {Lipid Panel Plus Reagent Disc} (Whole Blood)}	Abaxis, Inc.	Measures cholesterol, HDL cholesterol, glucose, alanine aminotransferase, aspartate aminotransferase, and triglycerides in whole blood
82523QW	Ostex International Osteomark NTX Point of Care Prescription Home Use	Ostex International Inc.	Measures normalized cross-linked N-telopeptides of type 1 collagen in urine
82565QW	Abbott i-STAT Crea Cartridge {Whole Blood}	Abbott Point of Care	Quantitative measurement of creatinine in whole blood
82565QW, 84520QW	Abaxis Piccolo xpress Chemistry Analyzer (Kidney Check Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of creatinine and urea nitrogen in whole blood

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82565QW, 82947QW, 82950QW, 82951QW, 82952QW, 82977QW, 84450QW, 84460QW, 84520QW	1. Abaxis Piccolo Blood Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}	Abaxis, Inc.	Quantitative measurement of alanine aminotransferase, aspartate aminotransferase, creatinine, gamma-glutamyl transferase, glucose and urea nitrogen in whole blood
	2. Abaxis Piccolo xpress Chemistry Analyzer (General Chemistry 6 Panel){Whole Blood}	Abaxis, Inc.	
82679QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions.), 83002QW	Clearplan Easy Fertility Monitor (for luteinizing hormone and estrone 3 glucuronide)	Unipath Limited	Detection of luteinizing hormone and estrone 3 glucuronide in urine to identify the optimal time for conception
82947QW, 82950QW, 82951QW, 82952QW	1. HemoCue B-Glucose Photometer	HemoCue, Inc.	Measures glucose levels in whole blood
82947QW, 82950QW, 82951QW, 82952QW (cont.)	2. HemoCue® Glucose 201 Microcuvettes and Glucose 201 Analyzer	HemoCue, Inc.	
	3. Abbott i-STAT G Cartridge {Whole Blood}	Abbott Point of Care	
82962, 82465QW (Contact your Medicare carrier for claims instructions.)	Roche Diagnostics Accutrend Plus System {fingerstick whole blood}	Roche Diagnostics	Monitoring of blood glucose levels and cholesterol
82962, 82985QW	1. LXN Duet Glucose Control Monitoring System	LXN Corporation	Monitoring of blood glucose levels and measures fructosamine, which is used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period
	2. LXN IN CHARGE Diabetes Control System	LXN Corporation	
82985QW	LXN Fructosamine Test System	LXN Corporation	Used to evaluate diabetic control, reflecting diabetic control over a 2-3 week period (Not a useful test for screening diabetes mellitus)

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
82947QW	<ol style="list-style-type: none"> <li>1. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home Glucose test strips)</li> <li>2. Poylmer Technology Systems, Inc., CardioChek Home Test Systems (CardioChek Home eGLU test strips)</li> <li>3. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels Glucose test strips)</li> <li>4. Poylmer Technology Systems, Inc., CardioChek Plus Test Systems (PTS Panels eGLU test strips)</li> </ol>	<p>Polymer Technology Systems, Inc.</p> <p>Polymer Technology Systems, Inc.</p> <p>Polymer Technology Systems, Inc.</p> <p>Polymer Technology Systems, Inc.</p>	Measures glucose in whole blood
83001QW	<p>Gonadotropin, follicle stimulating (reproductive hormone) level - Refer to the FDA website  <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.</p>	Various	Detects follicle stimulating hormone in urine
83036QW	<p>Hemoglobin A1C level - Refer to the FDA website  <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.</p>	Various	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes. This semi-automated, benchtop system also and low concentrations of albumin in urine (microalbuminuria), creatinine in urine, and the albumin/creatinine ratio in urine.
83037QW	<p>Hemoglobin A1C level, by device for home use - Refer to the FDA website  <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.</p>	Various	Measures the percent concentration of hemoglobin A1c in blood, which is used in monitoring the long-term care of people with diabetes using devices cleared by the FDA for home use

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TESTS GRANTED WAIVED STATUS UNDER CLIA

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83516QW	1. Rapid Pathogen Screening, Inc. InflammaDry	Rapid Pathogen Screening, Inc.	Detection of elevated levels of the MMP-9 protein in human tears, from patients suspected of having dry eye.
82044QW	2. Quidel Corporation, InflammaDry Urine microalbumin (protein) analysis - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.	Quidel Corporation Various	Determination of low concentrations of albumin in urine by immunoassay, which is helpful for early detection in patients at risk for developing renal disease
83605QW	KDK Corporation Lactate Pro System	KDK Corporation	Quantitative measurement of lactate in whole blood
83655QW	ESA Biosciences LeadCare II Blood Lead Testing System (whole blood)	ESA Biosciences, Inc.	Quantitative measurement of blood lead in whole blood
83718QW, 84478QW, 82947QW, 82950QW, 82951QW, 82952QW	Polymer Technology Systems CardioChek PA Analyzer (PTS Panels Metabolic Chemistry Panel Test Strips)	Polymer Technology Systems, Inc.	Measures HDL cholesterol, triglycerides, and glucose in whole blood
83721QW	Polymer Technology Systems Cardiochek PA Analyzer	Polymer Technology Systems, Inc.	Measures LDL cholesterol in whole blood
83861QW	TearLab Corporation TearLab Osmolarity System	TearLab Corporation	Impedance measurement of tear fluid to provide an indirect assessment of osmolarity.
83880QW	1. Biosite Triage Meter {Whole Blood} 2. Biosite Triage Meter Plus {Whole Blood}	Biosite Incorporated	Quantitative measurement of B-type natriuretic peptide (BNP)
83986QW	All qualitative color comparison pH testing - body fluids (other than blood) 1. Dale Medical Products, Inc. RightLevel pH 2. Dale Medical Products, Inc. RightSpot pH	Various EZ-NG, LLC. EZ-NG, LLC.	pH detection (acid-base balance) in body fluids such as semen, amniotic fluid, and gastric aspirates Gastric pH detection (acid-base balance)

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\* Newly added waived test system

TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
83986QW(continued)	3. RightBio Metrics, RightSpot Infant pH Indicator	Right BioMetrics	
	4. RightBio Metrics, RightSpot pH Detector	Right BioMetrics	
83986QW (cont.)	5. RightBio Metrics, RightSpot pH Indicator	Right BioMetrics	Gastric pH detection (acid-base balance)
83986QW	Body fluid pH level, vaginal - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.	Various	Vaginal pH detection (acid-base balance)
84443QW	Blood test, thyroid stimulating hormone (TSH) - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems and analytes.	Screening Devices Canada Inc.	Qualitative determination of human thyroid stimulating hormone (TSH) in whole blood, which is a rapid TSH assay for hypothyroidism screening in adults
84450QW, 84520QW	Arkray SPOTCHEM EZ Chemistry Analyzer{whole blood}	Arkray, Inc.	Quantitative determination of blood urea nitrogen (BUN) and aspartate aminotransferase in whole blood
84450QW	Cholestech LDX Aspartate Aminotransferase (AST)(SGOT)	Cholestech Corporation	Quantitative determination of aspartate aminotransferase in whole blood
84460QW	Cholestech LDX® Alanine Aminotransferase (ALT) Test	Cholestech Corporation	Quantitative determination of alanine aminotransferase in whole blood
84478QW	Germaine Laboratories Inc. AimStrip Tandem Lipid Profile and Glucose Measuring System (Germaine Laboratories Inc. AimStrip Tandem Triglycerides Test Strips)	Germaine Laboratories Inc.	Measures triglycerides in whole blood
84703QW	Bayer Clinitek 50 Urine Chemistry Analyzer - for HCG, urine	Bayer Corp.	Diagnosis of pregnancy

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
84550QW	ForaCare, Inc. FORA MD6 Uric Acid Monitoring System (ForaCare, Inc. FORA MD6 Uric Acid Test Strips)	TaiDoc Technology Corp.	Measures blood uric acid in whole blood
85014QW	Wampole STAT-CRIT Hct	Wampole Laboratories	Screen for anemia
85018QW	Measures hemoglobin in whole blood. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various.	Tests for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K2EDTA, K3EDTA, sodium citrate, lithium heparin, or sodium heparin) of adults.
85025QW	Sysmex XW-100	Sysmex America, Inc.	Quantitative automated hematology analyzer intended using anticoagulated venous whole blood for WBC count, RBC count, hematocrit, hemoglobin, platelet count and WBC differential
85576QW	Accumetrics VerifyNow Aspirin Assay	Accumetrics Inc.	Qualitative assay to measure platelet aggregation
85610QW (Contact your Medicare carrier for claims instructions.)	Screening test for deficiency of prothrombin - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Aid in screening for congenital deficiencies of Factors II, V, VII, X; screen for deficiency of prothrombin; evaluate heparin effect, coumadin or warfarin effect; screen for Vitamin K deficiency. The <i>in vitro</i> diagnostic test provides quantitative prothrombin time (PT) results, expressed in seconds and INR units. It uses fresh capillary whole blood. It is intended for use by health care professionals at the point of care to monitor patients who are on warfarin-type (coumarin) anticoagulation therapy.
86294QW	1. Bion Diagnostic Sciences BTA stat Test (for home use)  2. LifeSign Status BTA	Bion Diagnostic Sciences, Inc.  Polymedco, Inc.	Immunoassay for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer, and used as an aid in the management of bladder cancer patients

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\* Newly added waived test system

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86308QW	Screening test for mononucleosis (mono) categorized as waived complexity - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Qualitative screening test for the presence of heterophile antibodies in human whole blood, which is used as an aid in the diagnosis of infectious mononucleosis
86318QW	Immunoassay for <i>Helicobacter pylori</i> antibodies, single step method, categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
86386QW	<ol style="list-style-type: none"> <li>Abbott Diagnostics Scarborough Inc. NMP22 BladderChek Test (Prescription Home Use) and (Professional Use)</li> <li>Alere NMP22 BladderChek Test (Professional Use)</li> <li>Matritech, Inc. NMP22® BladderCheck™ Test for Professional and Prescription Home Use</li> </ol>	<p>Alere</p> <p>Maritech, Inc.</p>	Immunoassay for the qualitative detection of nuclear matrix protein NMP22 in urine for use as an aid in monitoring bladder cancer patients
86618QW	<ol style="list-style-type: none"> <li>Wampole PreVue™ <i>B. burgdorferi</i> Antibody Detection Assay</li> <li>Quidel Sofia 2 {Fingerstick whole blood}</li> </ol>	<p>Wampole Laboratories</p> <p>Quidel Corporation</p>	Qualitative detection of IgG/IgM antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood
86701QW	<ol style="list-style-type: none"> <li>bioLytical INSTI HIV-1 Antibody Test {Fingerstick Whole Blood}</li> <li>OraSure Technologies OraQuick Rapid HIV-1 Antibody Test</li> </ol>	<p>BioLytical Laboratories, Inc.</p> <p>OraSure Technologies, Inc</p>	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1)

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## TESTS GRANTED WAIVED STATUS UNDER CLIA

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	3. OraSure OraQuick Rapid HIV-1 Antibody Test – fingerstick and venipuncture whole blood	OraSure Technologies, Inc.	
	4. Trinity Biotech Uni-Gold Recombigen HIV Test (Fingerstick, Venipuncture Whole Blood)	Trinity Biotech	
86769QW, 87426QW, 87811QW	1.Flowflex COVID-19 Antigen Home Test*	ACON Laboratories Inc.	Antigen Test is a visually read lateral flow immunoassay or immunofluorescent sandwich assay intended for the rapid, qualitative detection of SARS-CoV-2 virus nucleocapsid protein antigen directly in anterior nasal swab specimens from individuals with signs and symptoms of COVID19 within the first 6 days of symptom onset.
	2.Quidel Sofia 2*	Quidel Corporation	
86780QW	Diagnostics Direct LLC Syphilis Health Check {FingerStick Whole Blood}	Diagnostics Direct LLC	Immunochromatographic assay for the detection of <i>Treponema pallidum</i> (syphilis) antibodies in whole blood
86780QW, G0433QW	Chembio Diagnostic Systems, Inc., DPP HIV-Syphilis (Fingerstick whole blood)	Chembio Diagnostic Systems, Inc.	Immunoassay for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 (HIV-1/2), and/or <i>Treponema pallidum</i> bacteria
G0433QW	1. bioLytical Laboratories, INSTI HIV-1/HIV-2 Antibody Test {Fingerstick whole blood}	bioLytical Laboratories	Qualitative immunoassay to detect antibodies to Human Immunodeficiency Virus Type 1 (HIV-1) and Type 2 (HIV-2) in fingerstick whole blood, venipuncture whole blood and/or oral fluid specimens
	2. OraSure OraQuick Advance Rapid HIV-1/2 Antibody Test {oral fluid, fingerstick whole blood and venipuncture whole blood}	OraSure Technologies, Inc.	
	3. OraSure Technologies OraQuick In-Home HIV Test {Oral Fluid}	OraSure Technologies, Inc.	

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## TESTS GRANTED WAIVED STATUS UNDER CLIA

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	4. Chembio Diagnostic Systems, Inc. DPP HIV 1/2 Assay {Oral Fluid}	Chembio Diagnostic Systems, Inc.	
	5. Clearview Complete HIV 1/2 {Fingerstick Venipuncture, whole blood}	Chembio Diagnostic Systems, Inc.	
86803QW, G0472QW	OraQuick HCV Rapid Antibody Test and OraQuick Visual Reference Panel	Orasure Technologies Inc.	Qualitative immunoassay to detect antibodies to hepatitis C virus in fingerstick whole blood and venipuncture whole blood specimens
87077QW	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Presumptive identification of <i>Helicobacter pylori</i> in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)
87087QW-discontinued, see 87420QW			RSV antigen test
87210QW	1. Stesans Maybe?Mom Mini Ovulation Microscope	LEC Associates	Detects ferning pattern in saliva which is used in the determination of ovulation (optimal for conception)
	2. O2 Unlimited Donna Ovulation Tester	O2 Unlimited Corp.	
87338QW	Meridian Bioscience Immunocard STAT! HpSA (Stool)	Meridian Bioscience, Inc.	Immunoassay for rapid, qualitative detection of <i>Helicobacter pylori</i> antigens in stool
87389QW [from December 5, 2014 to December 31, 2014], 87806QW [on and after January 1, 2015], G0475QW [on and after January 1, 2017]	1. Organics, Alere Determine HIV-1/2 Ag/Ab Combo {fingerstick Whole Blood}	Organics	Detects antigen to HIV-1, and antibodies to HIV-1 and HIV-2 in whole blood

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## TESTS GRANTED WAIVED STATUS UNDER CLIA

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	2. Abbott Diagnostics Determine HIV-1/2 Ag/Ab Combo {Fingerstick whole blood}	Abbott Diagnostics	
87400QW	1. BD Veritor System for Rapid Detection of Flu A+B (For use with nasal and nasopharyngeal swabs) {Includes a Reader}	Becton, Dickinson and Company	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that differentiates between influenza types A and B
	2. Quidel Sofia 2 {Sofia Influenza A+B FIA}	Quidel Corporation	
87420QW	1. BD Veritor System for Rapid Detection of RSV (For use with nasopharyngeal specimens){Includes a reader}	Becton, Dickinson and Company	Rapid, qualitative detection of respiratory syncytial virus fusion protein directly from nasopharyngeal swab, and nasal aspirate specimens by lateral flow immunogold assay. The test is intended for use as an aid in the rapid laboratory diagnosis of acute respiratory syncytial virus infection in patients with symptoms consistent with RSV infection.
	2. Quidel Sofia 2 {Sofia RSV FIA}	Quidel Corp.	
	3. Rapid Check RSV Antigen Test (Nasopharyngeal swabs)	Healgen Scientific LLC	
	4. Versea Easy Lab PRO Rapid RSV Test*	Versea Diagnostics LLC	
	5. Clarity RSV Antigen Test*	Clarity Diagnostics LLC	
87430QW	1. BD Veritor System for Rapid Detection of Group A Strep (direct from throat swab)	Becton Dickinson and Company	Immunoassay for the detection of GAS antigen from throat swabs
	2. Quidel Sofia 2 {Sofia Strep A+ FIA} (from throat swab only)	Quidel Corporation	

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87449QW	ZymeTx Zstatflu® Test	Zymetx, Inc.	Qualitative determination of influenza types A and B from throat swab specimens that does not differentiate between types A and B
87502QW	Detection test by nucleic acid for multiple types influenza virus - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Differential and qualitative detection of Influenza A and Influenza B viral nucleic acids using isothermal nucleic acid amplification technology
87631QW	<ol style="list-style-type: none"> <li>1. Cepheid Gene Xpert Xpress System (Xpert Flu+RSV Xpress)</li> <li>2. Cepheid GeneXpert Xpress System (Xpert Xpress Flu/RSV Assay)(GeneXpert Xpress IV hub configuration)</li> <li>3. Roche Molecular, cobas Liat System cobas Liat Influenza A/B &amp; RSV Assay</li> <li>4. SPOTFIRE Respiratory Panel Mini *</li> <li>5. cobas Liat System {Cobas SARS-CoV-2 &amp; Influenza A/B}* </li> </ol>	<ol style="list-style-type: none"> <li>Cepheid</li> <li>Cepheid</li> <li>IQUUM, INC.</li> <li>Biofire Diagnostics</li> <li>Roche Molecular</li> </ol>	<p>Tests for RNA by reverse transcriptase polymerase chain reaction assay multiplexed polymerase chain reaction (PCR) intended for use for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids (3-5 targets ) in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection,</p>

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87633QW	1. BioFire Diagnostics, FilmArray 2.0 EZ Configuration Instrument (Viral and Bacterial Nucleic Acids){Nasopharyngeal Swabs}	BioFire Diagnostics, LLC	Multiplexed polymerase chain reaction (PCR) test for the simultaneous, qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swab (NPS) specimens (multiple types or subtypes, 12-25 targets) obtained from individuals with signs and symptoms of respiratory tract infection, including targets including Flu A and Flu B, RSV and COVID-19.
87634QW	1. Alere i System Respiratory Syncytial Virus	Alere Scarborough, Inc.	Qualitative detection of RSV viral RNA in direct nasopharyngeal swabs and nasopharyngeal swabs eluted in viral transport media utilizing isothermal nucleic acid amplification technology
	2. Alere ID NOW Instrument {Nasopharyngeal swabs}	Alere Scarborough, Inc.	
	3. Mesa Biotech Accula (Accula RSV Test)	Messa Biotech, Inc.	
	4. Sekisui Inc. Silaris Dock (Silaris RSV Test)	Messa Biotech, Inc.	
87635QW	1. Abbott ID NOW Instrument (Nasal and Nasopharyngeal Swabs)*	ABBOTT	Rapid molecular in vitro diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals with signs and symptoms of respiratory tract infection.
	2. Cue Health Monitoring System (For use with Anterior Nasal Swabs)*	Cue Health Inc.	
87651QW	1. Alere i Instrument	Alere Scarborough, Inc.	Detection of Group A bacterial nucleic acids utilizing isothermal nucleic acid amplification technology
	2. Alere i Instrument (Alere i Strep A 2)	Alere Scarborough, Inc.	
	3. Cepheid GeneXpert Xpress System (Xpert Xpress Strep A)(GeneXpert Xpress IV hub configuration)	Cepheid	

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## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87651QW (continued)	4. Mesa Biotech Accula {Accula Strep A Test}	Mesa Biotech	
	5. Roche Molecular, cobas Liat System	IQuum, Inc.	
87801QW	1. binx health io Instrument {For use with female vaginal swabs and male urine}	binx health limited	Detection of <i>Chlamydia trachomatis</i> and <i>Neisseria gonorrhoeae</i> DNA by polymerase chain reaction
	2. Visby Medical Sexual Health Click Test (For use with self-collected vaginal swabs)	Visby Medical	PCR-based assay for direct qualitative detection and differentiation of DNA from <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , and <i>Trichomonas vaginalis</i> .
	3. Visby Medical Sexual Health Test (For use with self-collected vaginal swabs)*	Visby Medical	PCR-based assay for direct qualitative detection and differentiation of DNA from <i>Chlamydia trachomatis</i> , <i>Neisseria gonorrhoeae</i> , and <i>Trichomonas vaginalis</i> in self-collected female vaginal swab
87804QW	Quidel QuickVue® Influenza Test	Quidel Corporation	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does not differentiate between influenza types A and B
87804QW	Qualitative detection of influenza type A and type B antigens that differentiates between influenza types A and B - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.	Various	Qualitative detection of influenza type A and type B antigens from nasal swab, nasopharyngeal (NP) swab, nasal wash, nasal aspirate or nasal specimens that does differentiate between influenza types A and B
87804QW	1. Binax Now® Flu A Test	Binax, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza A Test Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza A Test	SA Scientific, Inc.	Qualitative detection of influenza type A antigen in nasopharyngeal specimens
	4. SA Scientific SAS Influenza A Test	SA Scientific, Inc.	

This list includes updates from FFS13455

\* Newly added waived test system

## TESTS GRANTED WAIVED STATUS UNDER CLIA

<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87804QW	1. Binax Now® Flu B Test	Binax, Inc.	Qualitative detection of influenza type B antigen in nasopharyngeal specimens
	2. BTNX, Inc. Rapid Response Influenza BTest Cassette	SA Scientific, Inc.	
	3. EarlyDetect Pro Influenza B Test	SA Scientific, Inc.	
	4. SA Scientific SAS Influenza B Test	SA Scientific, Inc.	
87807QW	Qualitative detection of RSV antigen by immunoassay - Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the current waived complexity test systems.		Rapid immunoassay for the qualitative detection of RSV antigen
87808QW	1. Genzyme OSOM Trichomonas Rapid Test	Genzyme Corp.	Immunoassay for the qualitative detection of <i>Trichomonas vaginalis</i> antigens from vaginal swabs
	2. Sekisui Diagnostics, LLC OSOM Trichomonas Rapid Test	Genzyme Corp.	
87809QW	1. AdenoPlus (human eye fluid)	Rapid Pathogen Screening, Inc.	Immunochromatographic test for the qualitative detection of adenoviral antigens from eye fluid
	2. Quidel, AdenoPlus {Tear fluid}	Quidel Corp.	
	3. Quidel Corporation, QuickVue Adenoviral Conjunctivitis Test {Tear Fluid}	Quidel Corp.	
	4. Rapid Pathogen Screening RPS Adeno Detector	Rapid Pathogen Screening	

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<u>CPT CODE(S)</u>	<u>TEST NAME</u>	<u>MANUFACTURER</u>	<u>USE</u>
87880QW	Streptococcus group A antigen detection by immunoassay with direct optical observation categorized as waived complexity. Refer to the FDA website <a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm</a> for the currently waived complexity test systems.	Various	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
87899QW	Meridian Bioscience Immunocard STAT! HpSA {Stool}	Meridian Bioscience, Inc.	Immunoassay for the qualitative detection of <i>Helicobacter pylori</i> antigens in stool specimens
87905QW	Gryphus Diagnostics BVBlue	Gryphus Diagnostics, LLC	Enzyme activity test for the detection of sialidase activity in vaginal fluid specimens, an enzyme produced by bacterial pathogens such as <i>Gardnerella vaginalis</i> , <i>Bacteroides</i> spp., <i>Prevotella</i> spp., and <i>Mobiluncus</i> spp.
89300 QW (This test may not be covered in all instances. Contact your Medicare carrier for claims instructions)	1. Embryotech Laboratories FertilMARQ™ Home Diagnostic Screening Test for Male Infertility	Embryotech Laboratories, Inc.	Screening test to measure sperm concentration
	2. SpermCheck Vasectomy	Princeton BioMeditech Corp.	Detects sperm in semen following a vasectomy
	3. BonrayBio LensHooke X1 Semen Quality Analyzer	Dynamic Biotech Inc.	Detects sperm in semen
89321QW	1. Fertell Male Fertility Test	Genosis Ltd.	Determines whether the concentration of sperm is above a cut-off level
	2. Labcorp OnDemand Men's Rapid Fertility Test	MEDTOX Diagnostics Inc.	

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