



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. <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 the 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 very 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(a); 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 Benefits Policy Manual, Chapter 15 § 80>

2. Non-Physician Practitioners (NPPs)

- a. In 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.

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

(2) NPPs must maintain relationships with supervising and collaborating physician 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 act 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. <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 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 starting in 2017. Currently the reduction is 10 percent.
 - (i) Historically, during the period from January 1, 2018, through December 31, 2022, the reduction was 7 percent.
- 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, (behind Module 5)>

(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

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 referring physicians to the appropriate imaging service according to clinical circumstances.
 - (b) A listing of Clinical Decision Support Mechanisms is available on the CMS website at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html> <CMS Clinical Decision Support Mechanisms>
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 consulting 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 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 is 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 Brochure, Clinical Laboratory Improvement Amendments, ICN 006270, April 2009>

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 Brochure, Clinical Laboratory Improvement Amendments, ICN 006270, April 2009>

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 Brochure, Clinical Laboratory Improvement Amendments, ICN 006270, April 2009>

B. Payment for Clinical Diagnostic Laboratory Services

1. Medicare payment for clinical diagnostic laboratory services, 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 in 2018 will be equal to the weighted median private payor rate for each test. <MLN Matters, Clinical Laboratory Fee Schedule, Physician Payment Series>
 - a. Under the 2018 CLFS there will be no geographic adjustments to the payment amount
3. For dates of service prior to January 1, 2018, Medicare payment amount for a diagnostic laboratory service is based on the lesser of:
 - a. The actual charge;
 - b. The fee schedule amount for the applicable state or local geographic area; or
 - c. The national limitation amount ("NLA"). <Medicare Claims Processing Manual, Chapter 16 § 20>
 - (i) National limits are set at a percent of the median of all local fee schedule amounts for each laboratory test code.
4. 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>

5. 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>

6. Protecting Access to Medicare Act required significant changes to how Medicare determines the clinical lab fee schedule amount. <42 CFR Part 414>

- a. Under this law, HHS was required to develop regulations making Medicare payment for clinical lab tests equal to the median of private payor payments for the same.
- b. Effective January 1, 2018, clinical lab fee schedule rates are based on weighted median private payor rates.
- c. CLIA-certified laboratories that meet certain requirements are required to submit data on private payer payments for laboratory services to CMS. See MLN Matters article MMSE1619 for more details.
- d. Reduction rates are capped at 10% in 2020, and 15% in 2021 – 2023.

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

1. CLIA Number

- a. The CLIA number must be entered in 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) Exceptions¹

(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

¹ 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.

- (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; CoverageGenInfo/04_LabNCDs.asp>
 - (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

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

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

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

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

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

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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		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 M A C	Shared- System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
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 M A C	C E D I	C E D I	C E D I	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 http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ 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
PC	\$100	\$80	\$160 (\$100 + (.75 x \$80))	\$176 (\$100 + (.95 x \$80))
TC	\$500	\$400	\$700 (\$500 + (.50 x \$400))	\$700 (\$500 + (.50 x \$400))
Global	\$600	\$480	\$860 (\$600 + (.75 x \$80) + (.50 x \$400))	\$876 (\$600 + (.95 x \$80) + (.50 x \$400))

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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.*

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CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 738	Date: July 30, 2010
	Change Request 6993

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-

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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 E M A C	F I 	C A R R I E R	R H H I	Shared-System Maintainers				O T H E R
							F I S S	M C S	V M S	C 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 E M A C	F I 	C A R R I E R	R H H I	Shared-System Maintainers				O T H E R
							F I S S	M C S	V M S	C W F	
6993.3	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ 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						

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

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
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 $((\$500 + (.75 \times \$400))$	\$700 $((\$500 + (.5 \times \$400))$
Global	\$600	\$480	\$980 $((\$600 + \$480 - \$400) + (.75 \times \$400))$	\$880 $((\$600 + (\$480 - \$400) + (.5 \times \$400))$

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
		M A C	M A C				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	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
		M A C	M A C				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 http://www.cms.hhs.gov/MLNMattersArticles/ 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					

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Version 02/16/2023
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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).

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Version 02/14/2023
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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	
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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.

[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

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

Ellicott City, MD 21043
800-838-2110
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

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]

Version 02/15/2023
Check for Updates

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.¹⁸ 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.¹⁹ Further, these policies could provide the benefit of additional training opportunities for residents in rural settings, which have historically been in limited supply.²⁰ 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

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

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

²⁰ 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

OVERVIEW

What Is CLIA?

Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988, establishing quality standards for all non-research laboratory testing performed on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. CLIA requires that laboratories performing these types of tests be certified by the **Secretary of the Department of Health and Human Services (DHHS)**.

The **Centers for Medicare & Medicaid Services (CMS)** administers the CLIA laboratory certification program for the Secretary in conjunction with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). The FDA is responsible for test categorization and the CDC is responsible for CLIA studies, convening the Clinical Laboratory Improvement Advisory Committee (CLIAC), and provides scientific and technical support to CMS. CLIA is user fee funded; therefore, all costs of administering the program must be covered by the regulated facilities, including certificate and survey costs.

Why Is CLIA Important?

CLIA established quality standards for laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. CMS data indicates that CLIA has helped to improve the quality of testing in the United States. The total number of quality deficiencies decreased approximately 40% from the first laboratory survey to the second under CLIA. Similar findings were demonstrated in the review of proficiency testing (PT) data over time. CLIA regulations apply to laboratory testing in all settings including commercial, hospital, and physician office laboratories.

Does CLIA Only Apply to Laboratories Obtaining Payment through Medicare?

CLIA standards are national and are not Medicare-exclusive. CLIA applies to all providers rendering clinical laboratory services, whether or not Medicare claims are filed.

How Are Test Methods Categorized?

CLIA regulations are based on the complexity of the test method. Test methods are categorized into three levels of complexity:

- Waived Complexity;
- Moderate Complexity, including Provider-Performed Microscopy Procedures (PPMP); and
- High Complexity.

The more complicated the test, the more stringent the requirements. CLIA specifies quality standards for PT, facility administration, general laboratory systems, preanalytic, analytic, and postanalytic systems, personnel qualifications and responsibilities, quality control, quality assessment, and specific cytology provisions for laboratories performing moderate and/or high complexity tests.

How Does a Laboratory Enroll in the CLIA Program?

To enroll in the CLIA program, laboratories must:

- Complete an application;
- Pay applicable fees;
- Be surveyed, if applicable; and
- Become certified, if CLIA standards are met.

Fees are based on the type of certification requested, and for moderate and high complexity laboratories, the annual volume and types of testing performed. Specific information about enrolling in CLIA and the application form can be found at: <http://www.cms.hhs.gov/clia/>

Upon payment of fees, each laboratory is assigned an individual and unique CLIA number. For Medicare claims to be processed, the CLIA number must be reported on all claims for laboratory services.



TYPES OF CERTIFICATES

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The CLIA program has five types of laboratory certificates: Certificate of Waiver, Certificate for Provider-Performed Microscopy Procedures, Certificate of Registration, Certificate of Compliance, and Certificate of Accreditation.

Certificate of Waiver (CW)

The **Certificate of Waiver** permits a laboratory to perform only waived tests. Waived tests are those tests that have been determined so simple and accurate that there is little risk of error if the test is performed incorrectly. Examples of waived tests include certain testing methods for glucose and cholesterol, pregnancy tests, fecal occult blood tests, and some urine tests. Routine on-site surveys are not required for a CW Certificate unless there is a complaint but the laboratory must follow the manufacturer's instructions for test performance.

Certificate for Provider-Performed Microscopy Procedures (PPMP)

A subset of the Moderate Complexity tests, PPMPs are given a unique classification and certification. This certificate is issued to a laboratory in which a physician, midlevel practitioner, or dentist performs no tests other than certain microscopy procedures (a moderately complex procedure which is performed using a microscope; e.g., urine microscopic or KOH smear) and waived tests. This certificate permits the laboratory to also perform waived tests. Routine on-site surveys are not required for a PPMP Certificate, but these laboratories are subject to moderate complexity requirements and can be surveyed as part of a routine survey for nonwaived tests or a complaint is alleged.

Certificate of Registration (COR)

A Certificate of Registration is issued to a laboratory that applies for a Certificate of Compliance or a Certificate of Accreditation. A COR enables the laboratory to conduct moderate or high complexity laboratory testing or both until it is determined that the laboratory has met all requirements (through an on-site survey or verification of accreditation). Laboratories have a choice to achieve their CLIA certification via a CMS survey or a CMS approved accrediting organization.

Certificate of Compliance (COC)

A **Certificate of Compliance** is issued to a laboratory after an on-site survey finds that the laboratory is in compliance with all applicable CLIA requirements.

Laboratories with a Certificate of Compliance that perform moderate and/or high complexity testing are required to be surveyed biennially. Surveys are conducted by CMS or its agent and are outcome-oriented. CMS conducts surveys to determine a laboratory's regulatory compliance and assist laboratories in improving patient care through education and by emphasizing those standards that will have a direct impact on the laboratory's quality test performance. The surveyor determines whether the laboratory is meeting the requirements of the CLIA regulations based on:

- Observation of the laboratory's (past and current) practices;
- Interviews with the laboratory's personnel; and
- Review of the laboratory's relevant documented records.

Certificate of Accreditation (COA)

A laboratory that performs moderate and/or high complexity testing and that meets the standards of a private non-profit accreditation program approved by CMS may file for a COA. Approved non-profit accreditation programs are programs that are determined by CMS to have requirements that are equal to or more stringent than those of the CLIA program. The accreditation program inspects the laboratory on a biennial basis. Currently there are six CMS approved accrediting organizations. Periodically, each organization must be re-approved to ensure equivalency is maintained and each year CMS evaluates their performance in enforcing CLIA requirements to verify that it is sustained.

CLIA PERFORMANCE MEASURES— PROFICIENCY TESTING (PT)

By law, laboratories conducting moderate and/or high complexity testing are required to participate in PT.

PT is also educational and involves sending samples with results unknown to the laboratory, three times per year to evaluate whether the laboratory's results are accurate and compare to its peers. The CLIA regulation requires that the PT samples be tested in the same manner and by the same individuals as patient testing. PT samples are provided by private non-profit organizations, Federal, or State agencies. PT programs undergo an annual and ongoing regulatory review conducted by CMS.

WHERE CAN I FIND MORE INFORMATION

For more information on the Clinical Laboratory Improvement Amendments, please visit the following website:

CMS CLIA Information Page
<http://www.cms.hhs.gov/clia/>

This page contains information and links to a variety of CLIA resources including: CLIA regulations, CLIA enrollment, CLIA certificates, CLIA fee schedules, CLIA-approved accrediting organizations, CMS' outcome oriented survey process, data reports, key projects, CLIA performance measures, and CLIA State Agencies and CMS Regional Offices CLIA contacts.

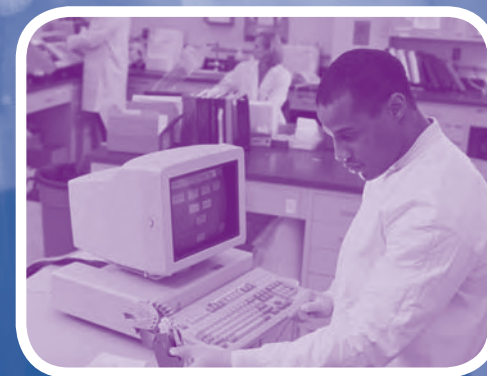
The Medicare Learning Network (MLN) is the brand name for official CMS educational products and information for Medicare providers. For additional information visit the Medicare Learning Network's Medlearn web page at <http://www.cms.hhs.gov/MLNGenInfo/> on the CMS website.

This brochure was prepared as a service to the public and is not intended to grant rights or impose obligations. This brochure may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

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Clinical Laboratory Improvement Amendments (CLIA)



CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Medicare
Learning
Network

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11735	Date: December 8, 2022
	Change Request 13024

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors about the new HCPCS codes for 2023 that are subject to and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, section 70.9.

EFFECTIVE DATE: April 1, 2023

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

IMPLEMENTATION DATE: April 3, 2023

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

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

III. FUNDING:

For Medicare Administrative Contractors (MACs):

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

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 11735	Date: December 8, 2022	Change Request: 13024
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SUBJECT: Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

EFFECTIVE DATE: April 1, 2023

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IMPLEMENTATION DATE: April 3, 2023

I. GENERAL INFORMATION

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

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

The following HCPCS codes were discontinued on March 31, 2022:

- 0097U - Test for detection of gastrointestinal disease-causing organism using amplified probe; and
- 0151U - Test for detection of respiratory disease-causing organisms in sputum or respiratory tract specimen, 33 target organismal and antibiotic resistance.

The following HCPCS codes were discontinued on September 30, 2022:

- 0012U - Gene analysis for germline disorder;
- 0013U - Gene analysis of solid organ tumor tissue;
- 0014U - DNA test for detecting gene abnormality associated with blood and lymphatic system cancer in blood or bone marrow; and
- 0056U - Whole genome sequencing in blood or bone marrow for acute myelogenous leukemia.

The HCPCS codes that follow are all subject to CLIA edits. These lists do not include new HCPCS codes for waived tests or provider-performed microscopy procedures. All these HCPCS codes require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests, unless a facility with a current CLIA certificate of waiver (certificate type code 2) or CLIA certificate for provider-performed microscopy procedures (certificate type code 4) bills the appropriate HCPCS service code with a QW modifier.

1. The HCPCS code listed below was added on February 21, 2022, and is subject to CLIA edits:

- 87913 - Genotype analysis of severe acute respiratory syndrome coronavirus 2 (COVID-19) by nucleic acid for identification of mutations in targeted regions.

1. The HCPCS codes listed below were added on April 1, 2022, and are subject to CLIA edits.

- 0306U - Initial baseline gene analysis for minimum residual disease in cancer, next-generation targeted sequencing analysis of cell-free DNA, to determine a patient specific panel for future comparisons;
- 0307U - Subsequent gene analysis for minimum residual disease in cancer, next-generation targeted sequencing analysis of cell-free DNA, to determine a patient specific panel for future comparisons;
- 0308U - Analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) in plasma specimen, algorithm reported as risk score for obstructive coronary artery disease;
- 0309U - Analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]) in plasma specimen, algorithm reported as risk score for major adverse heart event;
- 0310U - Analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake) for Kawasaki disease (KD) in plasma specimen, algorithm reported as risk score for KD;
- 0311U - Measurement of bacterial susceptibility to antibiotics, reported as phenotypic minimum inhibitory concentration (MIC) for each organism identified;
- 0312U - Analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products associated with autoimmune disease, using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence in serum specimen or plasma and whole blood specimen, individual components reported along with algorithmic systemic lupus erythematosus-likelihood assessment;
- 0313U - DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression in pancreatic cyst fluid specimen, algorithm reported as negative, low probability of cancer of pancreas or positive, high probability of cancer of pancreas;
- 0314U - mRNA gene expression profiling by real-time polymerase chain reaction (RT-PCR) of 35 genes (32 content and 3 housekeeping) associated with melanoma of skin in formalin-fixed paraffin-embedded (FFPE) tissue specimen, algorithm reported as benign, intermediate, or malignant;
- 0315U - mRNA gene expression profiling by real-time polymerase chain reaction (RT-PCR) of 40 genes (34 content and 6 housekeeping) associated with squamous cell carcinoma of skin in formalin-fixed paraffin-embedded (FFPE) tissue specimen, algorithm reported as benign, intermediate, or malignant;
- 0316U - Evaluation of outer surface protein A (OspA) of *Borrelia burgdorferi* (Lyme disease) in urine specimen;
- 0317U - Four-probe fluorescence in situ hybridization (FISH) (3q29, 3p22.1, 10q22.3, 10cen) assay of whole blood specimen, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer;
- 0318U - Whole genome methylation analysis by microarray for 50 or more genes associated with congenital epigenetic disorders in blood specimen;
- 0319U - RNA gene expression profiling by select transcriptome sequencing in peripheral blood specimen taken before kidney transplant, algorithm reported as risk score for early acute rejection;
- 0320U - RNA gene expression profiling by select transcriptome sequencing in peripheral blood specimen taken after kidney transplant, algorithm reported as risk score for acute cellular rejection;
- 0321U - Detection test by nucleic acid (DNA or RNA) multiplex amplified probe technique for identification of 20 bacterial and fungal organisms associated with genital or urinary tract infection and identification of 16 associated antibiotic-resistance genes; and
- 0322U - Measurement of 14 acyl carnitines and microbiome-derived metabolites associated with autism spectrum disorders by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in plasma specimen, results reported as negative or positive for risk of metabolic subtypes associated with autism spectrum disorders.

1. The HCPCS codes listed below were added on July 1, 2022, and are subject to CLIA edits.

- 0323U - DNA and mRNA next-generation sequencing analysis in cerebrospinal fluid specimen for detection of organisms causing disease in central nervous system;
- 0324U - Culture of spheroid ovarian cancer cells for evaluation of 4 drugs (carboplatin, doxorubicin, gemcitabine, paclitaxel), result reported as tumor chemotherapy response prediction for each drug;
- 0325U - Culture of spheroid ovarian cancer cells for evaluation of poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), result reported as tumor chemotherapy response prediction for each drug;
- 0326U - Targeted genomic sequence analysis of 83 or more genes in cell free circulating DNA for detection of abnormalities associated with solid organ cancers;
- 0327U - DNA sequence analysis of selected regions for detection of abnormal fetal chromosome number (trisomy 13, 18, and 21) in maternal plasma specimen, algorithm reported as risk score for each trisomy, includes sex reporting, if performed;
- 0328U - Definitive drug testing for 120 or more drugs and metabolites in urine specimen;
- 0329U - Exome and transcriptome sequence analysis of DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutations with therapy associations;
- 0330U - Amplified nucleic acid probe for identification of 27 vaginal disease agents in vaginal swab specimen; and
- 0331U - Optical genome mapping of DNA from blood or bone marrow specimen, report of clinically significant alterations associated with blood or lymph system cancers.

1. The HCPCS code listed below was added on July 26, 2022, and is subject to CLIA edits.

- 87593 - Infectious agent detection by nucleic acid (dna or rna); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each.

1. The HCPCS codes listed below were added on October 1, 2022, and are subject to CLIA edits.

- 0332U - Genetic profiling of 8 epigenetic markers to evaluate probability of responding to immune checkpoint-inhibitor therapy for cancer;
- 0333U - Surveillance for liver cancer in high risk patients using algorithm;
- 0334U - Targeted genomic sequence analysis of 84 or more genes for detection of abnormalities associated with cancer of body organ;
- 0335U - Whole genome sequence analysis of fetal sample for detection of abnormalities associated with rare constitutional/heritable diseases;
- 0336U - Whole genome sequence analysis of comparator genome (parent) for detection of abnormalities associated with rare constitutional/heritable diseases;
- 0337U - Evaluation of plasma cells for detection of abnormalities associated with plasma cell disorders and myeloma;
- 0338U - Evaluation of circulating solid tumor cells in peripheral blood;
- 0339U - mRNA expression profiling of genes associated with high-grade prostate cancer;
- 0340U - DNA assays for detection of minimal residual disease in cancer;
- 0341U - Fetal DNA sequencing of products of conception for detection of abnormal chromosome number;
- 0342U - Multiplex immunoassay for markers of pancreatic cancer in serum;

- 0343U - Exosome-based analysis of 442 small noncoding RNAs in urine to evaluate risk of prostate cancer;
- 0344U - Evaluation of 28 lipid markers for risk of nonalcoholic fatty liver disease;
- 0345U - Genomic analysis panel of 15 genes for detection of abnormalities associated with mental health disorders;
- 0346U - Evaluation of Beta amyloid AB40 and AB42 ratio;
- 0347U - DNA analysis of 16 genes involved in drug metabolism or processing;
- 0348U - DNA analysis of 25 genes involved in drug metabolism or processing;
- 0349U - DNA analysis of 27 genes involved in drug metabolism or processing, report including gene-drug interactions;
- 0350U - DNA analysis of 27 genes involved in drug metabolism or processing, analysis and reported phenotypes;
- 0351U - Biochemical assays for markers of bacterial infection; and
- 0352U - Detection of bacteria causing vaginosis and vaginitis by multiplex amplified nucleic acid probe technique.
- 0353U - Detection of Chlamydia trachomatis and Neisseria gonorrhoeae by multiplex amplified DNA probe technique; and
- 0354U - Human papilloma virus (HPV) by quantitative polymerase chain reaction (qPCR).

1. The HCPCS codes listed below were added on January 1, 2023, and are subject to CLIA edits.

- 0355U – Apol1 (apolipoprotein 11) (eg, chronic kidney disease), risk variants (g1, g2)
- 0356U – Oncology (oropharyngeal), evaluation of 17 dna biomarkers using droplet digital pcr (ddpcr), cell-free dna, algorithm reported as a prognostic risk score for cancer recurrence
- 0357U – Oncology (melanoma), artificial intelligence (ai)-enabled quantitative mass spectrometry analysis of 142 unique pairs of glycopeptide and product fragments, plasma, prognostic, and predictive algorithm reported as likely, unlikely, or uncertain benefit from immunotherapy agents;
- 0358U - Neurology (mild cognitive impairment), analysis of b-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative;
- 0359U - Oncology (prostate cancer), analysis of all prostate-specific antigen (psa) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer;
- 0360U - Oncology (lung), enzyme-linked immunosorbent assay (elisa) of 7 autoantibodies (p53, ny-eso-1, cage, gbu4-5, sox2, mage a4, and hud), plasma, algorithm reported as a categorical result for risk of malignancy;
- 0361U - Neurofilament light chain, digital immunoassay, plasma, quantitative;
- 0362U - Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture-enrichment rna sequencing of 82 content genes and 10 housekeeping genes, formalin-fixed paraffin embedded (ffpe) tissue, algorithm reported as one of three molecular subtypes;
- 0363U - Oncology (urothelial), mrna, geneexpression profiling by real-time quantitative pcr of 5 genes (mdk, hoxa13, cdc2 [cdk1], igfbp5, and excr2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma;
- 81418 - Genomic sequence analysis panel of at least 6 genes associated with drug metabolism;
- 81441 - Gene sequence analysis panel at least 30 genes associated with inherited bone marrow failure syndromes;
- 81449 - Targeted genomic sequence analysis panel of RNA of 5-50 genes associated with solid organ neoplasm;
- 81451 - Targeted genomic sequence analysis panel of RNA of 5-50 genes associated with blood and lymphatic system disorders;
- 81456 - Targeted genomic sequence analysis panel of RNA of 51 or greater genes associated with blood and lymphatic system disorders;
- 84433 - Evaluation of thiopurine S-methyltransferase (TPMT);

- 87467 - Measurement of Hepatitis B surface antigen (HBsAg);
- 87468 - Detection of Anaplasma phagocytophilum by amplified nucleic acid probe technique;
- 87469 - Detection of Babesia microtim by amplified nucleic acid probe technique;
- 87478 - Detection of Borrelia miyamotoi by amplified nucleic acid probe technique; and
- 87484 - Detection of Ehrlichia chaffeensis by amplified nucleic acid probe technique.

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

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

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

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13024.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.		X						X	
13024.2	Contractors shall deny payment for a claim submitted with the HCPCS codes mentioned above as subject to CLIA edits to a provider without valid current CLIA certificate, with a CLIA certificate of waiver (certificate type code 2) (when billed <u>without</u> the ‘QW’ modifier), or with a CLIA certificate for provider-performed microscopy procedures (certificate type code 4) (when billed <u>without</u> the ‘QW’ modifier).		X							
13024.3	Contractors shall return a claim as unprocessable if a CLIA number is not submitted on claims by providers for the HCPCS mentioned above as subject to CLIA edits.		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
13024.4	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
13024.5	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

Pre-Implementation Contact(s): Kathleen Todd, kathleen.todd@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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

ATTACHMENTS: 0

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