



Physician Services Version

KEY CONCEPTS OUTLINE

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

I. Medicare Coverage of Diagnostic Testing

A. In General

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

B. The Professional and Technical Components

1. In General

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

2. Determining if Separate Professional and Technical Components Are Billable

a. The “Modifier” Indicator

- (i) The Relative Value File contains a “modifier” indicator that, for diagnostic tests, defines whether CMS treats the test as divisible into separate professional and technical components. < See *Medicare Claims Processing Manual*, Chapter 23 Addendum, MPFSDB Record Layout>

- (a) For diagnostic tests, the modifier indicator will have one of the following values:

- (1) Nothing – a blank indicates a global service.

- (2) “-26” – indicates that the professional component of the test may be billed separately, or

- (3) “-TC” – indicates that the technical component of the test may be billed separately. <Medicare Claims Processing Manual, Chapter 23 Addendum, MPFSDB Record Layout>

- (b) For those HCPCS codes where the modifier indicator is -26 or -TC, the Relative Value File provides separate relative values and payment policy indicators for the global test (i.e., the combined professional and technical), the professional component only, and the technical component only.

b. PC/TC Indicator

- (i) The Relative Value File contains a “PC/TC” indicator that also defines whether CMS treats the test as divisible into separate professional and technical components. In order to bill properly for a diagnostic test, both the “modifier” indicator and the “PC/TC” indicator for the test should be reviewed.

- (a) The PC/TC indicator will have one of the following values: <Medicare Claims Processing Manual, Chapter 23 Addendum, MPFSDB Record Layout>

- (1) “1” – identifies the code as a diagnostic test that is divisible into separate professional and technical components using the 26/TC modifiers.

- (2) “2” – identifies the code as representing the professional component of a service that has separate HCPCS codes for the professional and technical components. Consequently, the 26/TC modifiers are not applicable to the code.

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

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

C. Physician Order Requirements for Diagnostic Tests

1. The General Rule

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

2. Exceptions

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

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

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

3. The Form of the Physician Order

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

D. Physician Supervision

1. The General Rule

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

2. Non-Physician Practitioners (NPPs)

- a. The 2021 Medicare Physician Fee Schedule Final Rule, finalized the COVID-19 PHE policy of NPP supervision of diagnostic testing that was set forth in the May 1, 2020, COVID -19 PHE Interim Final Rule <85 CFR 27550-27629>
 - (a) Nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse-midwives (CNMs), and certified registered nurse anesthetists (CRNAs) to supervise the performance of diagnostic tests. <See 410.32(b (1))>
 - (1) The diagnostic tests must be within the scope of practice and applicable to state law.
 - (2) NPPs must maintain relationships with supervising and collaborating physicians as required under Medicare statute.

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

3. Definition of the Three Levels of Physician Supervision

a. General Supervision

- (i) “General supervision” requires that the service be performed under the overall direction and control of the physician; however, the physician’s physical presence is not required during the performance of the test. <42 CFR § 410.32(b)(3)(i); Medicare Benefits Policy Manual, Chapter 15 § 80>
- (a) A physician who provides general supervision must have continuing responsibility for the training of the nonphysician personnel who actually perform the test and the maintenance of the necessary equipment and supplies. <42 CFR § 410.32(b)(3)(i); Medicare Benefits Policy Manual, Chapter 15 § 80>

b. Direct Supervision

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

c. Personal Supervision

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

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

- a. The Relative Value File contains a “physician supervision” indicator that indicates the required level of physician supervision for each diagnostic test. <Medicare Claims Processing Manual, Chapter 23 Addendum, MPFSDB Record Layout>
- (i) The physician supervision indicator will have one of the following values:
 - (a) “01” – requires general supervision,

- (b) “02” – requires direct supervision,
- (c) “03” – requires personal supervision, (For services rendered on or after 01/01/2019 diagnostic imaging procedures performed by a Registered Radiologist Assistant (RRA) who is certified and registered by the American Registry of Radiologic Technologists (ARRT) or a Radiology Practitioner Assistant (RPA) who is certified by the Certification Board for Radiology Practitioner Assistants (CBRPA), and is authorized to furnish the procedure under state law, may be performed under direct supervision)
- (d) “04” – physician supervision requirement does not apply when the service is furnished by a qualified, independent psychologist or a clinical psychologist, otherwise requires general supervision,
- (e) “05” – physician supervision requirement does not apply when the service is furnished by a qualified audiologist, otherwise requires direct physician supervision when furnished by a qualified technician,
- (f) “06” – service must be performed by a physician or a physical therapist who is certified by the American Board of Physical Therapy Specialties (ABPTS) as a qualified electrophysiological clinical specialist and is permitted to perform the service under state law,
- (g) “21” – service must be performed by a technician with certification under general supervision of a physician, otherwise requires direct supervision,
- (h) “22” – services may be performed by a technician with on-line real-time contact with physician.
- (i) “66” – services may be performed by a physician or by a physical therapist with ABPTS certification and certification in the specific procedure,
- (j) “6A” – supervision standards for level 66 apply; in addition, the PT with ABPTS certification may supervise another PT, but only the PT with ABPTS certification may bill,
- (k) “77” – services must be performed by a PT with ABPTS certification or by a PT without certification under the direct supervision of a physician, or by a technician with certification under general supervision of a physician,
- (l) “7A” – supervision standards for level 77 apply; in addition, the PT with ABPTS certification may supervise another PT, but only the PT with ABPTS certification may bill,

(m)“09” – the physician supervision concept does not apply. < See *Medicare Claims Processing Manual*, Chapter 23 Addendum, MPFSDB Record Layout; *Medicare Benefits Policy Manual*, Chapter 15 § 80>

II. Diagnostic Imaging Services

A. Implications of Physician Specialty

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

B. Written Report Requirement

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

C. Multiple Procedure Payment Reduction (MPPR)

1. In General

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

2. Technical Component Reduction

- a. The concept of eleven different “families” of imaging codes is retired. Now the affected imaging codes are grouped together into a single family whereby the technical component is subject to a 50% multiple procedure payment reduction when multiple technical component imaging procedures are performed during the same session. This policy became effective January 1, 2011. <*One-Time Notification Manual, Transmittal 738*>
- (i) Codes that are subject to the MPPR are identified on the Physician Fee Schedule with a multiple surgery value of “4” and an indicator of “88” in the Diagnostic Imaging Family field. <*One-Time Notification Manual, Transmittal 738*>
- b. The multiple procedure payment reduction was increased to 50% starting July 1, 2010, when performed during the same session and the procedures were included

within the same “family” of codes, the subsequent TC services furnished are reduced by 50 percent. <One-Time Notification Manual, Transmittal 694>

- c. When first introduced the technical component of certain subsequent diagnostic procedures was reduced by 25 percent (January 1, 2006, until June 30, 2010). <70 Fed. Reg. 70,263>

- (i) Definitions of the Families

- (a) The families were defined by body area, with procedures involving the same or contiguous body areas being grouped into the same family. The list of families, including the codes that fall within each family, was set forth in the physician fee schedule final rule. <73 Fed. Reg. 70,159>

3. Professional Component Reduction

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

4. Definition of “Same Session”

- a. For purposes of the imaging multiple procedure payment reduction, the term “same session” means “one encounter where a patient could receive one or more radiological studies.” <70 Fed. Reg. 70,262>

- (i) Where multiple imaging procedures are performed for the same patient on the same day, but during separate encounters (for medical reasons), the -59 modifier should be reported. Procedures reported with the -59 modifier will not be subject to the diagnostic multiple procedure payment reduction. <70 Fed. Reg. 70,263>
- (a) **Compliance caution** – CMS takes the position that scheduling patients for separate sessions to avoid the multiple procedure payment reduction constitutes fraud. <70 Fed. Reg. 70,263>

5. Application of the Reduction

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

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

- (i) CMS is incentivizing healthcare providers to transition from X-ray and computed radiography to digital radiography and in the process, help lower patient exposure to ionizing radiation.

- b. This law created a reduction in payment for organizations performing x-rays using film and computed radiography technology/cassette based imaging.
 - (i) X-rays utilizing film are subject to a 20 percent reduction which began on January 1, 2017.
 - (ii) Computed radiography technology/cassette-based imaging is currently subject to a 10 percent reduction (effective January 1, 2023).
 - (a) Historically from the effective date of January 1, 2018, through December 31, 2022, the reduction was set at seven percent. <Medicare Claims Processing Manual, Chapter 4 §§ 20.6.14 and 20.6.15>
- c. Providers are to indicate use of older technology through modifier reporting:
 - (i) FX – X-ray taken using film
 - (ii) FY – X-ray taken using computed radiography technology/cassette-based imaging

D. Certification for Suppliers of Advanced Diagnostic Imaging Services

1. In General

- a. Suppliers of the technical component of certain advanced diagnostic imaging services will need to be certified by January 1, 2012, in order to be eligible for reimbursement. <One Time Notification Manual, Transmittal 727>

2. Services Included

- a. Advanced diagnostic imaging services specifically included in this provision are:
 - (i) Diagnostic magnetic resonance imaging (MRI),
 - (ii) Computed tomography (CT), and
 - (iii) Nuclear medicine imaging, such as positron emission tomography (PET). <One Time Notification Manual, Transmittal 727>

3. Excluded Services

- a. Practitioners billing only for the professional interpretation of the advanced diagnostic imaging services are not required to be accredited.

b. Services that are specifically excluded from the accreditation requirement are:

- (i) X-ray,
- (ii) Ultrasound,
- (iii) Fluoroscopy services, and
- (iv) Mammography <One Time Notification Manual, Transmittal 727>

4. Accrediting Organizations

a. Suppliers may seek accreditation from one of the four organizations approved by CMS:

- (i) American College of Radiology (ACR)
- (ii) Intersocietal Accreditation Commission (IAC)
- (iii) The Joint Commission (TJC) <One Time Notification Manual, Transmittal 727>
- (iv) RadSite <CMS List of ADI Accrediting Organizations>

E. Computed Tomography (CT) Equipment Standards

1. Per the Protecting Access to Medicare Act of 2014 (PAMA), payments for the technical component of CT Scans furnished with equipment that does not meet the National Electrical Manufacturers Association (NEMA) Standard XR-29-2013 must be reduced effective January 1, 2016. <80 Fed Reg, November 16, 2015; MLN Matter MM9250>

a. Reduction in payment is 5% in 2016; 15% in 2017 & subsequent years

2. HCPCS Level II modifier to be used to indicate the service is performed using equipment that does not meet the NEMA Standard:

a. –CT - Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR-29-2013 standard

F. Supervision and Interpretation (“S&I”) Codes

1. Reporting S&I Codes

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

2. Split Supervision and Interpretation

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

G. Contrast

1. Background

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

2. Billing for the Supply of the Contrast Material

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

H. Mammography

1. Overview

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

2. Screening Versus Diagnostic Mammography

- a. Screening Mammography

(i) Definition

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

(ii) Coverage Issues

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

- (1) Age 35 - 39 – One baseline mammogram

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

- a. Example

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

(iii) Applicability of Part B Deductible and Coinsurance

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

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

(iv) Coding for Screening Mammography

- (a) CPT Coding

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

- (b) ICD-10-CM Diagnosis Coding

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

b. Diagnostic Mammography

(i) Definition

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

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

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

(c) Appropriate CPT Coding

(1) Bilateral diagnostic mammography

- a. Reported with CPT 77066 - Diagnostic mammography, including computer-aided detection (CAD) when performed; Bilateral); or

(2) Unilateral Diagnostic Mammography

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

c. Breast Tomosynthesis

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

(a) Screening Breast Tomosynthesis

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

(b) Diagnostic Breast Tomosynthesis

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

I. Appropriate Use Criteria in Advanced Diagnostic Imaging

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

1. The 2016 Medicare Physician Fee Schedule Final Rule announced the intent of CMS to implement an Appropriate Use Criteria program for Advanced Diagnostic Imaging services. The authority to do so by CMS comes from the Protecting Access to Medicare Act (PAMA). <80 Fed. Reg. November 16, 2015>
 - a. In section 1834(q)(1)(B) of PAMA, Appropriate Use Criteria are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decisions for a specific clinical condition.
 - b. Access to Medicare Act (PAMA) of 2014, Section 218(b), established a new program to increase the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries.
 - (i) Examples: computerized tomography, positron emission tomography, nuclear medicine, and magnetic resonance imaging.
 - (ii) Under this program, at the time a practitioner orders an advanced imaging service for a Medicare beneficiary, he/she will be required to consult a qualified Clinical Decision Support Mechanism (CDSM).
 - (a) CDSMs are digital tools that guide physicians to the appropriate imaging service according to clinical circumstances.
2. The 2018 Medicare Physician Fee Schedule Final Rule Finalized the following:
 - a. The Medicare AUC program will begin with an educational and operations testing year in 2020, requiring physicians to start using CDSMs and reporting this information on their claims.

- (i) CMS extended the education and operations through calendar year 2022. The AUC payment penalty phase has been suspended indefinitely at this time.

- (a) On November 11, 2023, CMS published the following statement:

- (1) *The payment penalty phase will not begin January 1, 2023, even if the PHE for COVID-19 ends in 2022. Until further notice, the educational and operations testing period will continue. CMS is unable to forecast when the payment penalty phase will begin.*

- b. During the education and operations testing years, CMS is proposing to pay claims for advanced diagnostic imaging services regardless of whether they correctly contain information on the required AUC consultation.
- c. CMS posted newly qualified provider-led entities and clinical decision support mechanisms in July of 2017.
 - (i) Qualified provider-led entities are permitted to develop AUC, and qualified clinical decision support mechanisms. <CMS Clinical Decision Support Mechanisms>
 - (ii) Voluntary participation period – Started July 1, 2018, and ran through 2019.
 - (a) During this time CMS collected limited information on Medicare claims to identify advanced imaging services for which consultation with appropriate use criteria took place.
 - (iii) The use of qualified clinical decision support mechanisms was credited under the Merit-Based Incentive Payment System as an improvement activity.

III. Clinical Diagnostic Laboratory Services

A. Clinical Laboratory Improvement Amendments (“CLIA”)

1. Definition

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

2. Importance of CLIA

- a. In general, any entity that tests human specimens and reports patient specific results, including physician offices, must register under CLIA to either obtain a

CLIA “certificate” or be deemed “CLIA-exempt” in order to bill and be paid for laboratory services furnished to Medicare (or Medicaid) beneficiaries. <42 CFR § 493.3(a)>

- (i) A CLIA-exempt laboratory is “a laboratory that has been licensed or approved by a state where CMS has determined that the state has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the state licensure program has been approved by CMS.” <42 CFR § 493.2>

- (a) While CLIA-exempt laboratories do not need to obtain a CLIA certificate, they must still register and are still subject to many of the requirements of CLIA (e.g., inspections). <42 CFR § 493.5>

3. CLIA Certificate Application

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

4. Types of CLIA Certificates

a. Certificate of Waiver

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

(a) Definition of “Waived Tests”

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

- a. Are cleared by FDA for home use,

- b. Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or
 - c. Pose no reasonable risk of harm to the patient if the test is performed incorrectly. <42 CFR § 493.15(a); *Medicare Claims Processing Manual*, Chapter 16 § 70.8>
- (2) A current list of CLIA waived tests is available on the CMS's CLIA web page.
 - a. Not every CPT code in the 80000 series is subject to CLIA edits. CMS maintains a list of codes in the 80000 series which are exempt from the CLIA edits. <*One-Time Notification Manual*, Transmittal 882>
- b. Certificate for Provider-Performed Microscopy Procedures
 - (i) Issued to a laboratory that performs:
 - (a) Only those tests designated as provider-performed microscopy procedures, and
 - (b) CLIA waived tests. <42 CFR §§ 493.2(d)(2); 413.19; *Medicare Claims Processing Manual*, Chapter 16 § 70.6>
- c. Certificate of Registration
 - (i) Issued to a laboratory that performs moderate or high complexity laboratory testing pending issuance of a Certificate of Compliance or a Certification of Accreditation. <42 CFR § 493.2(d)(4); MLN 006270, May 2023>
- d. Certificate of Compliance
 - (i) Issued to a laboratory that has been found to be in compliance with the CLIA requirements for applicable levels of testing. <42 CFR § 493.2(d)(1); *MLN* 006270, May 2023>
- e. Certificate of Accreditation
 - (i) Issued to a laboratory by a CMS approved accrediting organization whose standards at least meet, if not exceed, the applicable CLIA requirements. <42 CFR § 493.2(d)(3); *MLN* 006270, May 2023>

B. Payment for Clinical Diagnostic Laboratory Services

1. Medicare payment for clinical diagnostic laboratory services,(CLFS), including lab services furnished by physicians/practitioners, is made under the “Clinical Diagnostic Laboratory Services Fee Schedule” rather than the Physician Fee Schedule.
<Medicare Claims Processing Manual, Chapter 16 § 20>
 - a. Not all CPT codes found in the 80000 series of the CPT Manual are considered clinical diagnostic laboratory services. Some 80000 series codes are still paid under the Physician Fee Schedule when furnished through a physician/practitioner office. <Medicare Claims Processing Manual, Chapter 16 § 100.2>
2. The Medicare payment amount for a diagnostic laboratory service testing is equal to the weighted median private payor rate for each test. <MLN Fact Sheet: Clinical Laboratory Fee Schedule, MLN006818>
 - a. The private payor rate-based CLFS began January 1, 2018.
 - (i) Ended previous geographic adjustments to CLFS payment rates.
 - (ii) Payments are based on the applicable information collected and reported. The data collection, reporting, and payment updates generally take place every three years.
 - (a) CLIA-certified laboratories that meet certain requirements are required to submit data on private payer payments for laboratory services to CMS.
 - (iii) When median private payor rates are less than previous CLFS payment for specific clinical diagnostic laboratory testing, payments will be adjusted.
 - (a) CMS regulations limit the rate reduction amounts for most CDLTs when compared to the preceding year’s payment rate.
 - (1) For CYs 2023-2025, the reduction is limited to 15 percent. <42 CFR §414.507(d)>
 - (2) Historical reduction rates were capped at 10% in 2020, with no reduction in CYs 2021 and 2022.
3. Laboratory Tests are Subject to Mandatory Assignment
 - a. A physician, laboratory or medical group must accept assignment for laboratory tests paid under the Laboratory Fee Schedule. <Medicare Claims Processing Manual, Chapter 16 § 30.1>

4. Deductible and Coinsurance

- a. Neither the annual Part B deductible, nor the usual Part B coinsurance requirement applies to the following services:
 - (i) Clinical laboratory tests performed by the physician, lab, or other entity paid on an assigned basis;
 - (ii) Specimen collection fees; or
 - (iii) Travel allowances related to laboratory tests. <Medicare Claims Processing Manual, Chapter 16 § 30.2>

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

1. CLIA Number

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

2. Date of Service

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

(1) For archived specimens, the date of service should be the date the specimen was “obtained from the archives.” <Medicare Claims Processing Manual, Chapter 16 § 40.8(A)>

a. A specimen is considered an “archived specimen” if it was stored more than 30 days before testing. <Medicare Claims Processing Manual, Chapter 16 § 40.8(A)>

(c) Extended Collection Period

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

(d) Advanced Diagnostic Laboratory Tests and Molecular Pathology Tests

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

3. Repeat Testing on the Same Day

a. Limitations on Payment for Repeat Tests

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

b. Modifier Usage

(i) Modifiers -59 (distinct procedural service) or -91 (repeat clinical lab test) are used to indicate that a service was performed more than once on the same day for the same patient. <Medicare Claims Processing Manual, Chapter 16 § 100.5.1>

(a) The -91 modifier may be used to indicate that a repeat lab test was distinct or separate from a lab panel or other lab services performed on the same day and was performed to obtain subsequent reportable test values. <Medicare Contractor Beneficiary and Provider Communications Manual, Chapter 5 § 20.4.3 Example 2.a; Medicare Claims Processing Manual, Chapter 16 § 100.5>

- (1) It appears that CMS intends for the modifier -91 to be used with services paid under the Laboratory Fee Schedule. <Medicare Claims Processing Manual, Chapter 16 § 100.5.1>
 - a. However, the -91 modifier does not appear to be limited just to services paid on the Laboratory Fee Schedule since the Medicare Contractor Beneficiary and Provider Communications Manual, Chapter 5 § 20.4 provides an example suggesting that -91 should be used with cytopathology services (which are paid under the Physician Fee Schedule rather than the Clinical Diagnostic Laboratory Fee Schedule).

D. Organ/Disease Panels

1. Definition

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

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

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

3. Panels Not Covered by Medicare

- a. The following CPT panels are omitted from the Clinical Diagnostic Laboratory Fee Schedule:
 - (i) Code 80050 (general health panel)
- b. CMS appears to take the position that the omitted panel is not a Medicare benefit – presumably because they relate to preventative services. <Program Memorandum AB-97-23>

- (i) However – Medicare may cover one or more of the individual tests included in these panels if the individual tests are medically necessary. <Program Memorandum AB-97-23; Program Memorandum AB-98-71>

4. Billing for Panels

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

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

1. Definition

- a. The lab NCDs are national coverage policies for clinical diagnostic laboratory tests. <Medicare Claims Processing Manual; Chapter 16 § 120.2>
- b. The lab NCDs are set forth in a special Medicare National NCD manual for laboratory services. <CMS web site page; www.cms.gov/medicare/coverage/coverageegeninfo/labncdsicd10 >
- (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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