

|   |   |
|---|---|
| <b>CMS Manual System</b>                  | <b>Department of Health &amp; Human Services (DHHS)</b>   |
| <b>Pub 100-02 Medicare Benefit Policy</b> | <b>Centers for Medicare &amp; Medicaid Services (CMS)</b> |
| <b>Transmittal 11901</b>                  | <b>Date: March 16, 2023</b>                               |
|   | <b>Change Request 13094</b>                               |

**SUBJECT: Update to the Manual to Clarify Supervision Requirements for Diagnostic Tests**

**I. SUMMARY OF CHANGES:** The purpose of this Change Request (CR) is to clarify existing manual language. We are revising the manual to clarify that Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Nurse-Midwives (CNMs), Certified Registered Nurse Anesthetists (CRNAs) and Physician Assistants (PAs) may supervise the performance of diagnostic tests.

**EFFECTIVE DATE: January 1, 2021**

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

**IMPLEMENTATION DATE: May 17, 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.

| <b>R/N/D</b> | <b>CHAPTER / SECTION / SUBSECTION / TITLE</b>  |
|--------------|--|
| R            | 15/ 80/ Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests |

**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. 100-02 | Transmittal: 11901 | Date: March 16, 2023 | Change Request: 13094 |
|-------------|--------------------|----------------------|-----------------------|

**SUBJECT: Update to the Manual to Clarify Supervision Requirements for Diagnostic Tests**

**EFFECTIVE DATE: January 1, 2021**

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

**IMPLEMENTATION DATE: May 17, 2023**

## I. GENERAL INFORMATION

**A. Background:** The purpose of this CR is to update changed provisions to the diagnostic tests benefit category under section 1861(s)(3) of the Social Security Act and Federal regulations at 42 CFR 410.32. Specifically, in the Calendar Year (CY) 2021 Physician Fee Schedule (PFS) final rule, Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Nurse-Midwives (CNMs), Certified Registered Nurse Anesthetists (CRNAs) and Physician Assistants (PAs) were authorized to supervise the performance of diagnostic tests in addition to physicians.

Furthermore, the CY 2021 PFS final rule reiterated policy that allows NPs, CNSs and PAs when personally performing diagnostic tests to do so in accordance with the supervision requirements under their respective statutory benefit category.

**B. Policy:** Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, *as a basic rule*, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare. *However, effective January 1, 2021, this basic rule regarding individuals supervising the performance of diagnostic tests also includes nurse practitioners, clinical nurse specialists, certified nurse-midwives, certified registered nurse anesthetists and physician assistants.*

*When nurse practitioners, clinical nurse specialists, and physician assistants personally perform diagnostic tests as provided under §1861(s)(2)(K) of the Act, the supervision requirements under §1861(s)(3) of the Act and under 42 CFR 410.32 do not apply. Rather, these practitioners are authorized to personally perform diagnostic tests under the supervision requirements applicable to their practitioner benefit category pursuant to State scope of practice laws and under the applicable State requirements.*

Because the diagnostic tests benefit category set forth in §1861(s)(3) of the Act is separately enumerated and distinct from the “incident to” benefit category set forth in §1861(s)(2)(A) of the Act, diagnostic tests cannot be billed to the Medicare program as “incident to” services. Accordingly, the supervision requirements under the “incident to” benefit category are not applicable to the diagnostic tests benefit category.

## II. BUSINESS REQUIREMENTS TABLE

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

| Number  | Requirement   | Responsibility |   |     |            |                           |     |     |     |       |
|---------|---|----------------|---|-----|------------|---------------------------|-----|-----|-----|-------|
|         |   | A/B MAC        |   |     | DME<br>MAC | Shared-System Maintainers |     |     |     | Other |
|         |   | A              | B | HHH |            | FISS                      | MCS | VMS | CWF |       |
| 13094.1 | Contractors shall be aware of the updates listed in this CR for | X              | X |     |            |                           |     |     |     |       |

| Number | Requirement                | Responsibility |   |     |            |                           |     |     |     |       |
|--------|----------------------------|----------------|---|-----|------------|---------------------------|-----|-----|-----|-------|
|        |                            | A/B MAC        |   |     | DME<br>MAC | Shared-System Maintainers |     |     |     | Other |
|        |                            | A              | B | HHH |            | FISS                      | MCS | VMS | CWF |       |
|        | Chapter 15 of Pub. 100-02. |                |   |     |            |                           |     |     |     |       |

**III. PROVIDER EDUCATION TABLE**

| Number  | Requirement   | Responsibility |   |     |            |      |
|---------|---|----------------|---|-----|------------|------|
|         |   | A/B MAC        |   |     | DME<br>MAC | CEDI |
|         |   | A              | B | HHH |            |      |
| 13094.2 | 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              | X |     |            |      |

**IV. SUPPORTING INFORMATION**

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

*"Should" denotes a recommendation.*

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

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

**V. CONTACTS**

**Pre-Implementation Contact(s):** Sartini Patrick, 410-786-9252 or patrick.sartini@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**

## 80 - Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

*(Rev.11901; Issued: 03-16-23; Effective: 01-01-21; Implementation: 05-17-23)*

This section describes the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is not a hospital inpatient. For hospital outpatient diagnostic services, the supervision levels assigned to each CPT or Level II HCPCS code in the Medicare Physician Fee Schedule Relative Value File that is updated quarterly, apply as described below. For more information, see Chapter 6 (Hospital Services Covered Under Part B), §20.4 (Outpatient Diagnostic Services).

Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare.

*However, effective January 1, 2021, the basic rule at 42 CFR 410.32(b)(1) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in §1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, certified nurse-midwife, certified registered nurse anesthetist or physician assistant. Services furnished without the required level of supervision are not reasonable and necessary.*

The regulation defines these levels of supervision for diagnostic tests as follows:

**General Supervision** - means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

**Direct Supervision** - in the office setting means the physician (*or other supervising practitioner*) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (*or other supervising practitioner*) must be present in the room when the procedure is performed.

**Personal Supervision** - means a physician must be in attendance in the room during the performance of the procedure.

One of the following numerical levels is assigned to each CPT or HCPCS code in the Medicare Physician Fee Schedule Database:

- 0 Procedure is not a diagnostic test or procedure is a diagnostic test which is not subject to the physician supervision policy.
- 1 Procedure must be performed under the general supervision of a physician.
- 2 Procedure must be performed under the direct supervision of a physician.
- 3 Procedure must be performed under the personal supervision of a physician. (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).

4 Physician supervision policy does not apply when procedure is furnished by a qualified, independent psychologist or a clinical psychologist or furnished under the general supervision of a clinical psychologist; otherwise must be performed under the general supervision of a physician.

5 Physician supervision policy does not apply when procedure is furnished by a qualified audiologist; otherwise must be performed under the general supervision of a physician.

6 Procedure must be performed by a physician or by a physical therapist (PT) who is certified by the American Board of Physical Therapy Specialties (ABPTS) as a qualified electrophysiologic clinical specialist and is permitted to provide the procedure under State law.

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.

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.

9 Concept does not apply.

21 Procedure must be performed by a technician with certification under general supervision of a physician; otherwise must be performed under direct supervision of a physician.

22 Procedure may be performed by a technician with on-line real-time contact with physician.

66 Procedure must be performed by a physician or by a PT with ABPTS certification and certification in this specific procedure.

77 Procedure must be performed by a PT with ABPTS certification or by a PT without certification under direct supervision of a physician, or by a technician with certification under general supervision of a physician.

*When nurse practitioners, clinical nurse specialists, and physician assistants personally perform diagnostic tests as provided under §1861(s)(2)(K) of the Act, the supervision requirements under §1861(s)(3) of the Act and under 42 CFR 410.32 do not apply. Rather, these practitioners are authorized to personally perform diagnostic tests under the supervision requirements applicable to their practitioner benefit category pursuant to State scope of practice laws and under the applicable State requirements.*

Because the diagnostic tests benefit *category* set forth in §1861(s)(3) of the Act is separately *enumerated* and distinct from the “incident to” benefit *category* set forth in §1861(s)(2)(A) of the Act, diagnostic tests *cannot be billed to the Medicare program as “incident to” services. Accordingly, the supervision requirements under the “incident to” benefit category are not applicable to the diagnostic tests benefit category.*