| CMS Manual System | **Department of Health & Human Services (DHHS)** |
|---|---|
| Pub 100-02 Medicare Benefit Policy | **Centers for Medicare & Medicaid Services (CMS)** |
| **Transmittal 128** | **Date: May 28, 2010** |
| | **Change Request 6996** |

**SUBJECT: July 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**I. SUMMARY OF CHANGES:** This Recurring Update Notification updates and applies to Pub.100-02, Medicare Benefit Policy Manual, Chapter 6, sections 20.4 and 20.5 to further clarify CMS policies requiring physician supervision of diagnostic and therapeutic services provided to hospital outpatients. CMS recently updated these sections to reflect changes in these policies that were implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60588 through 60591). In this current update, CMS is further clarifying CMS CY 2010 policies in response to additional questions and comments received since publication of that rule. Specifically, clarification regarding supervision of diagnostic tests by non-physician practitioners is discussed. CMS also further defines the term immediately available, and clarifies the credentials, knowledge, skills, ability, and privileges that the supervisory practitioner must possess in order to be qualified to perform a given service or procedure.

**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

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|---|---|
| **R** | 6/20.4.3/Coverage of Outpatient Diagnostic Services Furnished on or Before December 31, 2009 |
| **R** | 6/20.4.4/Coverage of Outpatient Diagnostic Services Furnished on or After January 1, 2010 |
| **R** | 6/20.4.5/Outpatient Diagnostic Services Under Arrangements |
| **R** | 6/20.5.1/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000, and Before January 1, 2010 |
| **R** | 6/20.5.2/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010 |

**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:**

**Manual Instruction**

**Recurring Update Notification**

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

# Attachment – Recurring Update Notification

| Pub. 100-02 | Transmittal: 128 | Date: May 28, 2010 | Change Request: 6996 |
|---|---|---|---|

**SUBJECT: July 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)**

**Effective Date: July 1, 2010**

**Implementation Date: July 6, 2010**

## I. GENERAL INFORMATION

**A. Background:** This Recurring Update Notification updates Pub.100-02, Medicare Benefit Policy Manual, chapter 6, sections 20.4 and 20.5 to further clarify CMS' policies requiring physician supervision of diagnostic and therapeutic services provided to hospital outpatients. CMS recently updated these sections to reflect changes in these policies that were implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60588 through 60591). In this current update, CMS is further clarifying CMS' CY 2010 policies in response to additional questions and comments received since publication of that rule. Specifically, clarification regarding supervision of diagnostic tests by non-physician practitioners is discussed. CMS also further defines the term "immediately available," and clarifies the credentials, knowledge, skills, ability, and privileges that the supervisory practitioner must possess in order to be qualified to perform a given service or procedure. Finally, CMS clarifies what constitutes a therapeutic service in the hospital outpatient department, including observation.

Note that CMS decided not to enforce the requirements for direct supervision of therapeutic services that are furnished to outpatients in critical access hospitals (CAHs) during calendar year 2010 (for more information, see http://www.cms.hhs.gov/HospitalOutpatientPPS/Downloads/WebNotice.pdf ).

**B. Policy:**

**1. Hospital Outpatient Diagnostic Services**

This instruction incorporates revisions to Pub.100-02, Medicare Benefit Policy Manual, chapter 6, section 20.4 to reflect changes in policies for physician supervision of hospital outpatient diagnostic services that were discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60588 through 60591).

**2. Hospital Outpatient Therapeutic Services**

This instruction incorporates revisions to Pub.100-02, Medicare Benefit Policy Manual, chapter 6, section 20.5, to reflect changes in policies for physician supervision of hospital outpatient therapeutic services that were discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60578 through 60588).

## II. BUSINESS REQUIREMENTS TABLE

*Use "Shall" to denote a mandatory requirement*

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 6996.1 | Medicare contractors shall refer to the Medicare Benefit Policy Manual, Pub.100-02, Chapter 6, Sections 20.4 and 20.5 for the latest revisions. | X | | X | | X | | | | | |

## III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility (place an "X" in each applicable column) | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | A/B MAC | DME MAC | FI | CARRIER | RHHI | Shared-System Maintainers | | | | OTHER |
| | | | | | | | FISS | MCS | VMS | CWF | |
| 6996.2 | 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.<br>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 | | X | | | | | |

## IV. SUPPORTING INFORMATION

**Section A: For any recommendations and supporting information associated with listed requirements, use the box below: None**
*Use "Should" to denote a recommendation.*

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

**Section B: For all other recommendations and supporting information, use this space: None**

## V. CONTACTS

**Pre-Implementation Contact(s):** Marina Kushnirova at marina.kushnirova@cms.hhs.gov

**Post-Implementation Contact(s):** Appropriate Regional Office

## VI. FUNDING

**Section A: 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.

**Section B: *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.

## 20.4.3 - Coverage of Outpatient Diagnostic Services Furnished on or Before December 31, 2009

***(Rev.128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)***

Covered diagnostic services to outpatients include the services of nurses, psychologists, technicians, drugs and biologicals necessary for diagnostic study, and the use of supplies and equipment. When a hospital sends hospital personnel and hospital equipment to a patient's home to furnish a diagnostic service, Medicare covers the service as if the patient had received the service in the hospital outpatient department.

For services furnished before August 1, 2000, hospital personnel may provide diagnostic services outside the hospital premises without the direct personal supervision of a physician. For example, if a hospital laboratory technician is sent by the hospital to a patient's home to obtain a blood sample for testing in the hospital's laboratory, the technician's services are a covered hospital service even though a physician was not with the technician.

For services furnished on or after August 1, 2000, and before January 1, 2010, Medicare Part B makes payment for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

1. They are furnished by the hospital or under arrangements made by the hospital or CAH with another entity (see *section* 20.1 of this chapter);

2. They are ordinarily furnished by, or under arrangements made by the hospital or CAH to its outpatients for the purpose of diagnostic study;

3. They would be covered as inpatient hospital services if furnished to an inpatient; and

4. Payment is allowed under the hospital outpatient prospective payment system for diagnostic services furnished at a facility that is designated as provider-based only when those services are furnished under the appropriate level of supervision specified in accordance with the definitions at 42 CFR 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii), and as described in Chapter 15 of this manual, Section 80 "Requirements for Diagnostic X-ray, Diagnostic Laboratory, and Other Diagnostic Tests," as though they are being furnished in a physician's office or clinic setting. With respect to individual diagnostic tests, the supervision levels listed in the quarterly updated Medicare Physician Fee Schedule (MPFS) Relative Value File apply. For diagnostic services not listed in the MPFS, Medicare contractors, in consultation with their medical directors, define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary.

Future updates to the MPFS relative value files will be issued in future Recurring Update Notifications.

As specified at 42 CFR 410.28(f), for services furnished on or after February 21, 2002, the provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of 42 CFR 410.32 apply to all diagnostic laboratory tests furnished by hospitals and CAHs to outpatients.

*Physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives who operate within the scope of practice under State law may order and perform diagnostic tests, as discussed in 42 CFR 410.32(a)(2) and corresponding guidance in chapter 15, section 80 of this manual. However, this manual guidance and the long established regulation at 42 CFR 410.32(b)(1) also state that diagnostic x-ray and other diagnostic tests must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Some of these non-physician practitioners may perform diagnostic tests without supervision, see the regulation at 410.32(b)(2) and 42 CFR 410.32(b)(3). Thus, while physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives only require physician supervision included in any collaboration or supervision requirements particular to that type of practitioner when they personally perform a diagnostic test, these practitioners are not permitted to function as supervisory "physicians" for the purposes of other hospital staff performing diagnostic tests.*

## 20.4.4 - Coverage of Outpatient Diagnostic Services Furnished on or After January 1, 2010

***(Rev.128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)***

Covered diagnostic services to outpatients include the services of nurses, psychologists, technicians, drugs and biologicals necessary for diagnostic study, and the use of supplies and equipment. When a hospital sends hospital personnel and hospital equipment to a patient's home to furnish a diagnostic service, Medicare covers the service as if the patient had received the service in the hospital outpatient department.

As specified at 42 CFR 410.28(a), for services furnished on or after January 1, 2010, Medicare Part B makes payment for hospital or CAH diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services (even if those drugs or biologicals are self-administered), if those services meet the following conditions:

1. They are furnished by the hospital or under arrangements made by the hospital or CAH with another entity (see section 20.1 of this chapter);

2. They are ordinarily furnished by, or under arrangements made by the hospital or CAH to its outpatients for the purpose of diagnostic study; and

3. They would be covered as inpatient hospital services if furnished to an inpatient.

As specified at 42 CFR 410.28(e), for services furnished on or after January 1, 2010, payment is allowed under the hospital outpatient prospective payment system for diagnostic services only when those services are furnished under the appropriate level of *physician* supervision specified in accordance with the definitions at 42 CFR 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii). Under general supervision, the training of the nonphysician personnel who actually perform the

diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the facility.

*Physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives who operate within the scope of practice under State law may order and perform diagnostic tests, as discussed in 42 CFR 410.32(a)(2) and corresponding manual guidance in chapter 15, section 80 of this manual. However, this manual guidance and the long established regulation at 42 CFR410.32(b)(1) also state that diagnostic x-ray and other diagnostic tests must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Some of these non-physician practitioners may perform diagnostic tests without supervision, see 410.32(b)(2) and (3). Thus, while physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives only require physician supervision included in any collaboration or supervision requirements particular to that type of practitioner when they personally perform a diagnostic test, these practitioners are not permitted to function as supervisory ''physicians'' for the purposes of other hospital staff performing diagnostic tests.*

With respect to individual diagnostic tests, the supervision levels listed in the quarterly updated MPFS Relative Value File apply. For diagnostic services not listed in the MPFS, Medicare contractors, in consultation with their medical directors, define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary. Future updates to the MPFS Relative Value Files will be issued in future Recurring Update Notifications. For guidance regarding the numeric levels assigned to each CPT or HCPCS code in the MPFS Relative Value File, see Chapter 15 of this manual, *Section* 80, "Requirements for Diagnostic X-ray, Diagnostic Laboratory, and Other Diagnostic Tests."

For services furnished directly or under arrangement in the hospital or in an on-campus outpatient department of the hospital, as defined at 42 CFR 413.65, "direct supervision" means that the physician must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. This definition is specified at 42 CFR 410.28(e)(1). For this purpose, the definition of "in the hospital" is as specified at 42 CFR 410.27(g).

For services furnished directly or under arrangement in an off-campus outpatient department of the hospital, as defined at 42 CFR 413.65, "direct supervision" means the physician must be present in the off-campus provider-based department of the hospital and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. This definition is specified at 42 CFR 410.28(e)(2).

For services furnished under arrangement in nonhospital locations, "direct supervision" means the definition specified at 42 CFR 410.32(b)(3)(ii).

*Immediate availability requires the immediate physical presence of the physician. CMS has not specifically defined the word "immediate" in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician is*

*performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician may not be so physically far away on-campus from the location where hospital outpatient services are being furnished that he or she could not intervene right away.*

*The supervisory physician must have, within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the primary operators of some specialized diagnostic testing equipment, and while in such cases CMS does not expect the supervisory physician to operate this equipment instead of a technician, the physician that supervises the provision of the diagnostic service must be knowledgeable about the test and clinically appropriate to furnish the test.*

*The supervisory responsibility is more than the capacity to respond to an emergency, and includes the ability to take over performance of a procedure and, as appropriate to the supervisory physician and the patient, to change a procedure or the course of care for a particular patient. CMS would not expect that the supervisory physician would make all decisions unilaterally without informing or consulting the patient's treating physician or nonphysician practitioner. In summary, the supervisory physician must be clinically appropriate to supervise the service or procedure.*

As specified at 42 CFR 410.28(f), for services furnished on or after February 21, 2002, the provisions of paragraphs (a) and (d)(2) through (d)(4), inclusive, of 42 CFR 410.32 apply to all diagnostic laboratory tests furnished by hospitals and CAHs to outpatients.

## 20.4.5 - Outpatient Diagnostic Services Under Arrangements

***(Rev.128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)***

When the hospital makes arrangements with others for diagnostic services, such services are covered under Part B as diagnostic tests whether furnished in the hospital or in other facilities. *Diagnostic services furnished under arrangement in on-campus hospital locations, off-campus hospital locations, and in nonhospital locations must be furnished under the appropriate level of physician supervision according to the requirements of 42 CFR 410.28(e) and 410.32(b)(3), as discussed in section 20.4.4 above.*

Independent laboratory services furnished to an outpatient under arrangements with the hospital are covered only under the "diagnostic laboratory tests" provisions of Part B (see Section 10, above), but are to be billed along with other services to outpatients. See Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," Section 50.3, for: (1) the definition of an independent clinical laboratory; (2) the requirements which such a laboratory must meet; and (3) instructions to the intermediary when it is not approved. The "cost" to the hospital for diagnostic laboratory services for outpatients obtained under arrangements is the reasonable charge by the laboratory.

Laboratory services may also be furnished to a hospital outpatient under arrangements by:

1. The laboratory of another participating hospital; or

2. The laboratory of an emergency hospital or participating skilled nursing facility that meets the hospital conditions of participation relating to laboratory services.

## 20.5.1 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After August 1, 2000, and Before January 1, 2010

***(Rev.128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)***

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians and practitioners in the treatment of patients. *All hospital outpatient services that are not diagnostic are services that aid the physician or practitioner in the treatment of the patient.* Such *therapeutic* services include clinic services, emergency room services, *and observation services*. Policies for hospital services incident to physicians' services rendered to outpatients differ in some respects from policies that pertain to "incident to" services furnished in office and physician-directed clinic settings. See Chapter 15,"Covered Medical and Other Health Services," *section* 60.

To be covered as incident to physicians' services, the services and supplies must be furnished by the hospital or CAH or under arrangement made by the hospital or CAH (see *section* 20.1.1 of this chapter). The services and supplies must be furnished as an integral, although incidental, part of the physician or nonphysician practitioner's professional service in the course of treatment of an illness or injury.

The services and supplies must be furnished in the hospital or at a department of the hospital which has provider-based status in relation to the hospital under 42 CFR 413.65. The services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the Act, the Code of Federal Regulations, and State law, and furnished by hospital personnel under the direct supervision of a physician or clinical psychologist as defined at 42 CFR 410.32(b)(3)(ii) and 482.12. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician responsible for care of the patient. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.

The physician or clinical psychologist that supervises the services need not be in the same department as the ordering physician. For services furnished at a department of the hospital which has provider-based status in relation to the hospital under 42 CFR 413.65, "direct supervision" means the physician or clinical psychologist must be present and on the premises of the location (the provider-based department of the hospital) and immediately available to furnish

assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

If a hospital therapist, other than a physical, occupational or speech-language pathologist, goes to a patient's home to give treatment unaccompanied by a physician, the therapist's services would not be covered. See Chapter 15, "Covered Medical and Other Health Services," Sections 220 and 230, for outpatient physical therapy and speech-language pathology coverage conditions.

## 20.5.2 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010

***(Rev.128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)***

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities) which are incident to the services of physicians and practitioners in the treatment of patients. *All hospital outpatient services that are not diagnostic are services that aid the physician or practitioner in the treatment of the patient.* Such services include clinic services, emergency room services, *and observation services*. Policies for hospital services incident to physicians' services rendered to outpatients differ in some respects from policies that pertain to "incident to" services furnished in office and physician-directed clinic settings. See Chapter 15,"Covered Medical and Other Health Services," Section 60.

To be covered as incident to physicians' services, the services and supplies must be furnished by the hospital or CAH or under arrangement made by the hospital or CAH (see section 20.1.1 of this chapter). The services and supplies must be furnished as an integral, although incidental, part of the physician or nonphysician practitioner's professional service in the course of treatment of an illness or injury.

The services and supplies must be furnished in the hospital or at a department of the hospital which has provider-based status in relation to the hospital under 42 CFR 413.65. As specified at 42 CFR 410.27(g), "in the hospital or CAH" means areas in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital's or CAH's CMS Certification Number.

The services and supplies must be furnished under the order of a physician or other practitioner practicing within the extent of the Act, the Code of Federal Regulations, and State law, and furnished by hospital personnel under the direct supervision of a physician or nonphysician practitioner as defined at 42 CFR 410.27(f) and 482.12. This does not mean that each occasion of service by a nonphysician need also be the occasion of the actual rendition of a personal professional service by the physician responsible for care of the patient. However, during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, where necessary, to change the treatment regimen. A hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote

an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment.

The physician or nonphysician practitioner that supervises the services need not be in the same department as the ordering physician. Beginning January 1, 2010, according to 42 CFR 410.27(a)(1)(iv), in addition to physicians and clinical psychologists, licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, and a certified nurse-midwife may directly supervise *therapeutic* services that they may personally furnish in accordance with State law and all additional requirements, including those specified at 42 CFR 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77. These nonphysician practitioners are specified at 42 CFR 410.27(f).

For services furnished in the hospital or CAH or in an on-campus outpatient department of the hospital or CAH, as defined at 42 CFR 413.65, "direct supervision" means that the physician or nonphysician practitioner must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. This definition is specified at 42 CFR 410.27(a)(1)(iv)(A). For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or osteopathy, as specified at 42 CFR 410.47 and 410.49, respectively.

For services furnished in an off-campus outpatient department of the hospital or CAH, as defined at 42 CFR 413.65, "direct supervision" means the physician or nonphysician practitioner must be present in the off-campus provider-based department of the hospital or CAH and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. This definition is specified at 42 CFR 410.27(a)(1)(iv)(B). For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or osteopathy, as specified at 42 CFR 410.47 and 410.49, respectively.

*Immediate availability requires the immediate physical presence of the physician or nonphysician practitioner. CMS has not specifically defined the word "immediate" in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician or nonphysician practitioner is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician or nonphysician practitioner may not be so physically far away on-campus from the location where hospital/CAH outpatient services are being furnished that he or she could not intervene right away.*

*The supervisory physician or nonphysician practitioner must have, within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the primary operators of some specialized therapeutic equipment, and while in such cases CMS does not expect the supervisory physician or nonphysician practitioner to operate this equipment*

*instead of a technician, CMS does expect the physician or nonphysician practitioner to be knowledgeable about the therapeutic service and clinically appropriate to furnish the service.*

*The supervisory responsibility is more than the capacity to respond to an emergency, and includes the ability to take over performance of a procedure and, as appropriate to the supervisory physician or nonphysician practitioner and the patient, to change a procedure or the course of care for a particular patient. CMS would not expect that the supervisory physician or nonphysician practitioner would make all decisions unilaterally without informing or consulting the patient's treating physician or nonphysician practitioner. In summary, the supervisory physician or nonphysician practitioner must be clinically appropriate to supervise the service or procedure.*

*Direct supervision is the minimum standard for supervision of all Medicare hospital outpatient therapeutic services. Considering that hospitals furnish a wide array of very complex outpatient services and procedures, including surgical procedures, CMS would expect that hospitals already have the credentialing procedures, bylaws, and other policies in place to ensure that hospital outpatient services furnished to Medicare beneficiaries are being provided only by qualified practitioners in accordance with all applicable laws and regulations. For services not furnished directly by a physician or nonphysician practitioner, CMS would expect that these hospital bylaws and policies would ensure that the therapeutic services are being supervised in a manner commensurate with their complexity, including personal supervision where appropriate.*

If a hospital therapist, other than a physical, occupational or speech-language pathologist, goes to a patient's home to give treatment unaccompanied by a physician, the therapist's services would not be covered. See Chapter 15, "Covered Medical and Other Health Services," Sections 220 and 230 for outpatient physical therapy and speech-language pathology coverage conditions.