CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-02 Medicare Benefit Policy	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 143	**Date: April 29, 2011**
	Change Request 7354

SUBJECT: Manual Restructuring of Chapter 6, Section 20, Subsections 20.4.4, and 20.5.2

I. SUMMARY OF CHANGES: This Change Request restructures the CMS manual requirements for the supervision of diagnostic and therapeutic services provided to hospital outpatients.

No business requirements or substantive material has been deleted or added. This is strictly a structured consolidation of existing material from previous subsections 20.4.5 to 20.4.4, and 20.5.3 to 20.5.2. a result of this consolidation and to preserve the numbering format, section 20.4.6 is being deleted and the policy shifted to section 20.4.5.

EFFECTIVE DATE: May 31, 2011
IMPLEMENTATION DATE: May 31, 2011

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

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	6/Table of Contents
R	6/20/20.4.4/Coverage of Outpatient Diagnostic Services Furnished on or After January 1, 2010
R	6/20/20.4.5/Outpatient Diagnostic Services Under Arrangements
D	6/20/20.4.6/Outpatient Diagnostic Services Under Arrangements
R	6/20/20.5.2/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010
D	6/20/20.5.3/Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2011

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:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

Pub. 100-02	Transmittal: 143	Date: April 29, 2011	Change Request: 7354

SUBJECT: Manual Restructuring of Chapter 6, Section 20, Subsections 20.4.4, and 20.5.2

Effective Date: May 31, 2011

Implementation Date: May 31, 2011

I. GENERAL INFORMATION

A. Background: This Change Request restructures the CMS manual requirements for the supervision of diagnostic and therapeutic services provided to hospital outpatients.

B. Policy: CMS is making several revisions to chapter 6, section 20, subsections 20.4.4, and 20.5.2 to organize the existing requirements into fewer sections by the date on which the service is furnished. CMS is simply consolidating material that previously was separated into two sections (rules applying to services furnished in CY 2010, and rules applying to services furnished in CY 2011 and following) into one section (rules applying to services furnished after January 1, 2010).

No business requirements or substantive material has been deleted or added. This is strictly a structured consolidation of existing material from previous subsections 20.4.5 to 20.4.4, and 20.5.3 to 20.5.2. As a result of this consolidation and to preserve the numbering format, section 20.4.6 is being deleted and the policy shifted to section 20.4.5.

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	
7354.1	Contractors shall be aware of the restructuring of Pub. 100-02, Medicare Benefit Policy Manual, chapter 6, section 20, subsections 20.4.4, and 20.5.2	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	
	None.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
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: N/A

V. CONTACTS

Pre-Implementation Contact(s): Chuck Braver at chuck.braver@cms.hhs.gov or 410-786-6719

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: *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: *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.

Medicare Benefit Policy Manual
Chapter 6 - Hospital Services Covered Under Part B

Table of Contents
(Rev.143, Issued: 04-29-11)

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

(Rev. 143, Issued: 04-29-11, Effective: 05-31-11, Implementation: 05-31-11)

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), payment is allowed under the hospital outpatient prospective payment system for diagnostic services only when those services are furnished under the appropriate level of supervision specified in accordance with the definitions *in this manual and* at 42 CFR 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii) *of general, direct and personal supervision*. 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 *their* 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 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 and may not be supervised by nonphysician practitioners. Sections 410.32(b)(2) and (3) provide certain exceptions that allow some diagnostic tests furnished by certain non-physician practitioners to be furnished without physician supervision. While these nonphysician practitioners including physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives cannot provide the required physician supervision when other hospital staff are performing diagnostic tests, when these nonphysician practitioners personally perform a diagnostic service they must meet only the physician supervision requirements that are prescribed under the Medicare coverage rules at 42 CFR Part 410 for that type of practitioner when they directly provide a service. For example, under *section* 410.75 nurse practitioners

must work in collaboration with a physician, and under *section* 410.74 physician assistants must practice under the general supervision of a physician.

With respect to individual diagnostic tests, the supervision levels listed in the quarterly updated *Medicare Physician Fee Schedule (PFS)* Relative Value File apply. For diagnostic services not listed in the PFS, 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. Updates to the PFS 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 PFS Relative Value File, see Chapter 15 of this manual, Section 80, "Requirements for Diagnostic X-ray, Diagnostic Laboratory, and Other Diagnostic Tests."

For *diagnostic* services furnished *during calendar year (CY) 2010 whether* 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 *where the services are being furnished. For services furnished in an off-campus provider based department as defined at 42CFR413.65, he or she must be present within the off-campus provider based department. The physician must be* immediately available to furnish assistance and direction throughout the performance of the procedure. *T*he physician *does not have to* be present in the room when the procedure is performed. *"In the hospital" means the definition specified in 42CFR410.27(g), which is 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.*

For diagnostic services furnished during CY 2011 and following, whether directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital as defined at 42 CFR 413.65, "direct supervision" means that the physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. As discussed below, the physician is not required to be present in the room where the procedure is being performed or within any other physical boundary as long as he or she is immediately available.

For services furnished *during CY 2010 and following* under arrangement in nonhospital locations, "direct supervision" means the definition specified *in the PFS* at 42 CFR 410.32(b)(3)(ii). *The supervisory physician must remain present within the office suite where the service is being furnished and must be immediately available to furnish assistance and direction throughout the performance of the procedure. The supervisory physician is not required to be present in the room where the procedure is being performed.*

Immediate availability requires the immediate physical presence of the supervisory 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 hospital or supervisory physician must judge the supervisory physician's relative location to ensure that he or she is immediately available.*

For services furnished in CY 2011 and following, CMS permits direct supervision from any locations such as physician offices that are close to the hospital or provider based department of a hospital where the services are being furnished but are not located in actual hospital space, as long as the supervisory physician remains immediately available. Similarly, as of CY 2011 CMS permits direct supervision from any location in or near an off-campus hospital building that houses multiple hospital provider based departments where the services are being furnished as long as the supervisory physician is immediately available.

*The supervisory physician need not be in the same department as the ordering physician. Notwithstanding, t*he 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 *or provide additional orders.* 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. 143, Issued: 04-29-11, Effective: 05-31-11, Implementation: 05-31-11)

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 the applicable sections 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.

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

(Rev. 143, Issued: 04-29-11, Effective: 05-31-11, Implementation: 05-31-11)

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. *For therapeutic services furnished during CY 2010, 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.

Therapeutic 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. *They must be* furnished by hospital personnel under the *appropriate* supervision of a physician or nonphysician practitioner as *required in this manual and by* 42 CFR 410.27 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.

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 certified nurse-midwives may directly supervise therapeutic services that they may personally furnish in accordance with State law and all additional rules governing the provision of their services, including those specified at 42 CFR Part 410. These nonphysician practitioners are specified at 42 CFR 410.27(f).

*CMS requires direct supervision in the provision of all therapeutic services to hospital outpatients, including CAH outpatients by an appropriate physician or non-physician practitioner. Effective January 1, 2011, hospitals may change to general supervision for a portion of the non-surgical extended duration therapeutic services ("extended duration services") but only as specified in this manual for those services (see section 20.7). P*ulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services *require* direct supervision *which* must be furnished by a doctor of medicine or osteopathy, as specified at 42 CFR 410.47 and 410.49, respectively.

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.

For *therapeutic* services furnished *during CY 2010* 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 *where the services are being furnished. For services furnished in an off-campus provider based department as defined in 42CFR413.65, he or she must be present within the off-campus provider based department. The physician or nonphysician practitioner must be* immediately available to furnish assistance and direction throughout the performance of the procedure. *T*he physician or nonphysician practitioner *does not have to* be present in the room when the procedure is performed.

For therapeutic services furnished during CY 2011 and following, whether in the hospital or in an on-campus or off-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 immediately available to furnish assistance and direction throughout the performance of the procedure. As discussed below, the physician is not required to be present in the room where the

procedure is performed or within any other physical boundary as long as he or she is immediately available.

Immediate availability requires the immediate physical presence of the *supervisory* 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 hospital or supervisory practitioner must judge the supervisory practitioner's relative location to ensure that he or she is immediately available.*

For services furnished in CY 2011 and following, a supervisory practitioner may supervise from a physician office or other nonhospital space that is not officially part of the hospital campus *where the services are being furnished* as long as he or she remains immediately available. *Similarly, as of CY 2011,* an allowed practitioner can supervise from any location in or near an off-campus hospital building that houses multiple hospital provider-based departments *where the services are being furnished* as long as the supervisory practitioner is immediately available.

The *supervisory practitioner* need not be in the same department as the ordering physician. Notwithstanding, 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 *or provide additional orders.* 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.

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.