

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 152	Date: December 29, 2011
	Change Request 7672

SUBJECT: January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)

I. SUMMARY OF CHANGES: This Change Request implements several changes and clarifications in the manual requirements of chapter 6 for the provision of hospital outpatient therapeutic and diagnostic services finalized in the CY 2012 OPPS/Ambulatory Surgical Center (ASC) Final Rule.

EFFECTIVE DATE: January 1, 2012

IMPLEMENTATION DATE: January 3, 2012

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	6/20.4.4/Coverage of Outpatient Diagnostic Services Furnished on or After 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: 152	Date: December 29, 2011	Change Request: 7672
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SUBJECT: January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Effective Date: January 1, 2012

Implementation Date: January 3, 2012

I. GENERAL INFORMATION

A. Background: This Change Request implements several changes and clarifications in the manual requirements of chapter 6 for the provision of hospital outpatient therapeutic and diagnostic services, finalized in the CY 2012 OPSS/Ambulatory Surgical Center (ASC) Final Rule.

B. Policy:

1. Physician Supervision

In Pub. 100-02, Medicare Benefit Policy Manual, chapter 6, several revisions are being made to the standards governing the supervision of hospital or CAH outpatient therapeutic services. Currently, CMS requires direct supervision of these services except for nonsurgical extended duration therapeutic services (extended duration services), for which CMS allows general supervision during a portion of the service at the discretion of the supervising practitioner. To date, for purposes of the hospital outpatient setting CMS has only defined direct and general supervision, and CMS has only defined general supervision insofar as it applies to the provision of extended duration services. CMS is now providing that it may assign general or personal supervision for the duration of the service to certain hospital outpatient therapeutic services. To enable such assignment, CMS is defining those levels of supervision using the definitions that are used in the Medicare Physician Fee Schedule. Second, CMS is providing that as specified in its regulations, in addition to direct supervision certain non-physician practitioners may furnish the required general or personal supervision.

2. Definition of Hospital Outpatient Therapeutic Services

In the same section of the manual, CMS is slightly revising the language that is used in describing hospital outpatient therapeutic services, consistent with its clarification of the definition of these services in the CY 2012 OPSS/ASC Final Rule.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I I E R	C A R I E R	R H H I	Shared-System Maintainers				OTHER
					F I S S	M C S	V M S	C W F			
7672.02.1	Medicare contractors shall refer to Pub.100-02, Medicare Benefit Policy Manual, 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 M A C	D M M A C	F I I E R	C A R I E R	R H H I	Shared-System Maintainers				OTHER
					F I S S	M C S	V M S	C W F			
7672.02.2	<p>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.</p> <p>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.</p>	X		X		X					

IV. SUPPORTING INFORMATION

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

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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

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

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.

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

(Rev.152, Issued: 12-29-11, Effective: 01-01-12, Implementation: 01-03-12)

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.

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 42 CFR 413.65, 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. The physician does not have to be present in the room when the procedure is performed. “In the hospital” means the definition specified in 42CFR 410.27(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 *distant* 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, *which require* direct supervision, *the supervisory practitioner may be present in* 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 *for services requiring* direct supervision, *the supervisory practitioner may be present in* a 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 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 *able* 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.

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

(Rev. 152, Issued: 12-29-11, Effective: 01-01-12, Implementation: 01-03-12)

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities *and drugs and biologicals that cannot be self-administered*) which are *not diagnostic services, are furnished to outpatients* incident to the services of physicians and practitioners *and which aid them* in the treatment of patients. *These* services include clinic services, emergency room services, and observation services. Policies for hospital *outpatient therapeutic*

services *furnished* incident to physicians' services 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 *hospital outpatient therapeutic* 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 *that* 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.

Hospital outpatient 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, *when* 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.

CMS requires direct supervision (*defined below*) by an *appropriate physician or non-physician practitioner* in the provision of all therapeutic services to hospital outpatients, including CAH outpatients. *CMS may assign certain hospital outpatient therapeutic services either general supervision or personal supervision. When such assignment is made, "general supervision" means the definition specified at 42 CFR 410.32(b)(3)(i), that is, the procedure or service is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. "Personal supervision" means the definition specified at 42 CFR 410.32(b)(3)(iii), that is, the physician must be in attendance in the room during the performance of the service or procedure.*

Effective January 1, 2011, hospitals may change to general supervision for a portion of *services defined as* non-surgical extended duration therapeutic services ("extended duration services") but only as specified in this manual for those services (see section

20.7). Pulmonary 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.

Beginning January 1, 2010, according to 42 CFR 410.27, in addition to physicians and clinical psychologists, licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse-midwives may furnish *the required supervision of hospital outpatient* 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(g).

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 42 CFR 413.65, 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. The 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 CAH* 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 *distant* 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 *furnish direct supervision* from a physician office or other nonhospital space that is not officially part of the hospital *or CAH* 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 *furnish direct supervision* from any location in or near an off-campus hospital *or CAH* 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 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 *able* 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 *able* to supervise the service or procedure.