Medicare Benefit Policy - Basic Coverage Rules (PUB. 100-02)
Chapter 6 - Hospital Services Covered Under Part B
20 - Outpatient Hospital Services (Updated through Rev. 215, Effective: 01/01/16; Issued: 12/18/15)

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20 - Outpatient Hospital Services (Updated through Rev. 215, Effective: 01/01/16; Issued: 12/18/15)

(Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)

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Hospitals provide two distinct types of services to outpatients: services that are diagnostic in nature, and other services that aid the physician in the treatment of the patient. Part B covers both the diagnostic and the therapeutic services furnished by hospitals to outpatients. The rules in this section pertaining to the coverage of outpatient hospital services are not applicable to the following services.

- Physical therapy, speech-language pathology or occupational therapy services when they are furnished "as therapy" meaning under a therapy plan of care. See chapter 15, sections 220 and 230 of this manual, for coverage and payment rules for these services, which are paid at the applicable amount under the physician fee schedule.

- Services that are covered and paid under the End Stage Renal Disease Prospective Payment System. See Chapter 11, "End Stage Renal Disease (ESRD)" of this manual, for rules on the coverage of these services.

For policies in addition to this section that apply to partial hospitalization services, see chapter 6, section 70.3 of this manual, and Pub. 100-04, Medicare Claims Processing Manual, chapter 4, section 260.

For rules on the coverage of services and supplies furnished incident to a physician's professional services in an office or physician-directed clinic setting, refer to Chapter 15, "Covered Medical and Other Health Services," section 60 of this manual.

20.1 - Limitations on Coverage of Certain Services Furnished to Hospital Outpatients

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08) Sources: 42 CFR 410.42(a) and 64 FR 18536, April 7, 2000

20.1.1 - General Rule

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(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

Except as provided in section 20.1.2 of this chapter, Medicare Part B does not pay for any item or service that is furnished to a hospital outpatient, as defined in section 20.2, during an encounter, as defined in section 20.3, by an entity other than the hospital unless the hospital has arrangements with that entity to furnish that particular service to its patients. The arrangements must provide that Medicare payment made to the hospital

that arranged for the services discharges the liability of the beneficiary or any other person to pay for those services. See the Medicare General Information, Eligibility, and Entitlement Manual, Pub.100-01, chapter 5, section 10.3 for the definition of "arrangements." For the purposes of this section, the term "hospital" includes a Critical Access Hospital (CAH).

20.1.2 - Exception to Limitation

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(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

The limitation stated in section 20.1.1 does not apply to the following services:

- Physiciansâ€™ professional services that meet the following conditions:
- The services are personally furnished for an individual beneficiary by a physician;
- The services contribute directly to the diagnosis or treatment of an individual beneficiary;
- The services ordinarily require performance by a physician;
- In the case of radiology or laboratory services, additional requirements in

42 CFR §415.120 and 4§415.130, respectively of the Code of Federal Regulations are met.

- Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Social Security Act (the Act);
- Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act;
- Qualified psychologist services, as defined in section 1861(ii) of the Act;
- Services of an anesthetist, as defined in regulations in 42 CFR 410.69;
- Services furnished to SNF residents as defined in regulations in 42 CFR 411.15(p).

20.2 - Outpatient Defined

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(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

A hospital outpatient is a person who has not been admitted by the hospital as an inpatient but is registered on the hospital records as an outpatient and receives services (rather than supplies alone) from the hospital or CAH. Where a tissue sample, blood sample, or specimen is taken by personnel that are neither employed nor arranged for by the hospital and is sent to the hospital for performance of tests, the tests are not outpatient

hospital services since the patient does not directly receive services from the hospital. See section 70.5 for coverage of laboratory services furnished to nonhospital patients by a hospital laboratory unless the patient is also a registered hospital outpatient receiving outpatient services from the hospital on the same day and the hospital is not a CAH or Maryland waiver hospital. Similarly, supplies provided by a hospital supply room for use by physicians in the treatment of private patients are not covered as an outpatient service since the patients receiving the supplies are not outpatients of the hospital. (See the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 1,"Inpatient Hospital Services," section 10, for the definition of "inpatient.")

Where the hospital uses the category "day patient," i.e., an individual who receives hospital services during the day and is not expected to be lodged in the hospital at midnight, the individual is considered an outpatient. For information on outpatient observation status, refer to section 20.6 of this chapter and to the Medicare Claims Processing Manual, Pub.100-04, chapter 4, section 290, "Outpatient Observation Services." For information on conditions when an inpatient

admission may be changed to outpatient status, refer to the Medicare Claims Processing Manual, Pub.100-04, Chapter 1, "General Billing Requirements," section 50.3.

The inpatient of a SNF may be considered the outpatient of a participating hospital. However, the inpatient of a participating hospital cannot be considered an outpatient of that or any other hospital.

Outpatient hospital services furnished in the emergency room to a patient classified as "dead on arrival" are covered until pronouncement of death, if the hospital considers such patients as outpatients for record-keeping purposes and follows its usual outpatient billing practice for such services to all patients, both Medicare and non-Medicare. This coverage does not apply if the patient was pronounced dead prior to arrival at the hospital.

20.3 - Encounter Defined

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(Rev. 101, Issued: 01-16-09, Effective: 01-01-09, Implementation: 01-05-09) Source: 42 CFR 410.2 and 482.12

A hospital outpatient "encounter" is a direct personal contact between a patient and a physician, or other person who is authorized by State licensure law and, if applicable, by hospital or CAH staff bylaws, to order or furnish hospital services for diagnosis or treatment of the patient.

The conditions of participation for hospitals under 42 CFR 482.12(c)(1)(i) through
(c)(1)(vi) require that every Medicare patient is under the care of a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, a chiropractor, or a clinical psychologist; each practicing within the extent of the Act, the Code of Federal Regulations, and State law. Further, 42 CFR 482.12(c)(4) requires that a doctor of medicine or osteopathy must be responsible for the care of each Medicare patient with respect to any medical or psychiatric condition that is present on admission or develops during hospitalization and is not specifically within the scope of practice of one of the other practitioners listed in 42 CFR 482.12(c)(1)(i) through (c)(1)(vi).

20.4 - Outpatient Diagnostic Services

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

20.4.1 - Diagnostic Services Defined

Note: Minor inconsistencies may occur during PDF conversion process. You can also view this document in PDF.

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)

A service is "diagnostic" if it is an examination or procedure to which the patient is subjected, or which is performed on materials derived from a hospital outpatient, to obtain information to aid in the assessment of a medical condition or the identification of a disease. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury.

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

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(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

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(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 410.74physician 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.

20.4.5 - Outpatient Diagnostic Services Under Arrangements

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(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.

20.4.6 - Outpatient Diagnostic Services Under Arrangements

Note: Minor inconsistencies may occur during PDF conversion process. You can also view this document in PDF

(Rev.137, Issued: 12-30-10, Effective: 01-01-11, Implementation: 01-03-11)

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 - Outpatient Therapeutic Services

Note: Minor inconsistencies may occur during PDF conversion process. You can also view this document in PDF.

(Rev. 82; Issued: 02-08-08; Effective: 01-01-08; Implementation: 03-10-08)Sources: 42 CFR 410.27; 65 FR 18536, April 7, 2000

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

Note: Minor inconsistencies may occur during PDF conversion process. You can also view this document in PDF.

(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 x482.12. 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. 169, Issued: 03-01-13, Effective: 04-01-13, Implementation: 04- 01-13)

Note: Minor inconsistencies may occur during PDF conversion process. You can also view this document in PDF.

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 410.27and 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 410.47and 410.49, respectively.

The list of services that may be furnished under general supervision or that are defined as non-surgical extended duration therapeutic services is available on the OPPS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

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 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.

20.6 -Outpatient Observation Services

(Rev. 215, Issued, 12-18-15, Effective, 01-01-16, Implementation: 01-04-16)

A. Outpatient Observation Services Defined

Observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. Observation services are covered only when provided by the order of a physician or another individual authorized by State licensure law and hospital staff

bylaws to admit patients to the hospital or to order outpatient tests. In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient can be made in less than 48 hours, usually in less than 24 hours. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. Hospitals may bill for patients who are directly referred to the hospital for outpatient observation services. A direct referral occurs when a physician in the community refers a patient to the hospital for outpatient observation, bypassing the clinic or emergency department (ED) visit. Effective for services furnished on or after January 1, 2003, hospitals may bill for patients directly referred for observation services. See, Pub. 100-04, Medicare Claims Processing Manual, chapter 4, section 290, at http://www.cms.hhs.gov/manuals/downloads/clm104c04.pdf for billing and payment instructions for outpatient observation services. Future updates will be issued in a Recurring Update Notification.

B. Coverage of Outpatient Observation Services

When a physician orders that a patient receive observation care, the patient's status is that of an outpatient. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient (see Pub. 100-02, Medicare Benefit Policy Manual, Chapter 1, Section 10 "Covered Inpatient Hospital Services Covered Under Part A" at http://www.cms.hhs.gov/manuals/Downloads/bp102c01.pdf). For more information on correct reporting of observation services, see Pub. 100-04, Medicare Claims Processing Manual, chapter 4, section 290.2.2.)

All hospital observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare. Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). *As of* January 1, 2008, HCPCS code G0378 for hourly observation services is assigned status indicator N, signifying that its payment is always packaged. No separate payment is made for observation services reported with HCPCS code G0378. In most circumstances, observation services are supportive and ancillary to the other separately payable services provided to a patient. *Beginning January 1, 2016, in* certain circumstances when observation care is billed in conjunction with a clinic visit, Type A emergency department visit (Level *1 through* 5), Type B emergency department visit (Level *1 through* 5), critical care services, or direct referral for observation services as an integral part of a patient's extended encounter of care, *comprehensive* payment may be made for *all services on the claim including, the entire extended care encounter* when certain criteria are met. For information about billing and payment methodology for observation services in years prior to CY 2008, see Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §290.3-290.4. For information about payment for extended assessment and management under composite APCs *and comprehensive APCs*, see §290.5. Payment for all reasonable and necessary observation services is packaged into the payments for other separately payable services provided to the patient in the same encounter. Observation services packaged through assignment of status indicator N are covered OPPS services. Since the payment for these services is included in the APC payment for other separately payable services on the claim, hospitals must not bill Medicare beneficiaries directly for the packaged services.

C. Services Not Covered by Medicare and Notification to the Beneficiary

In making the determination whether an ABN can be used to shift liability to a beneficiary for the cost of non-covered items or services related to an encounter that includes observation care, the provider should follow a two step process. First, the provider must decide whether the item or service meets either the definition of observation care or would be otherwise covered. If the item or service does not meet the definitional requirements of any Medicare-covered benefit under Part B, then the item or service is not covered by Medicare and an ABN is not required to shift the liability to the beneficiary. However, the provider may choose to provide voluntary notification for these items or services. Second, if the item or service meets the definition of observation services or would be otherwise covered, then the provider must decide whether the item or service is "reasonable and necessary" for the beneficiary on the occasion in question, or if the item or service exceeds any frequency limitation for the particular benefit or falls outside of a timeframe for receipt of a particular benefit. In these cases, the ABN would be used to shift the liability to the beneficiary (see Pub. 100-04, Medicare Claims Processing Manual; Chapter 30, "Financial Liability Protections," Section 20, at

http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf for information regarding Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Disallowed). If an ABN is not issued to the beneficiary, the provider may be held liable for the cost of the item or service unless the provider/supplier is able to demonstrate that they did not know and could not have reasonably been expected to know that Medicare would not pay for the item or service.

20.7 - Non-Surgical Extended Duration Therapeutic Services

Rev. 169, Issued: 03-01-13, Effective: 04-01-13, Implementation: 04- 01-13)

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CMS designates a limited set of therapeutic services meeting specific criteria as nonsurgical extended duration therapeutic services ("extended duration services"), defined in 42 CFR 410.27(a)(1)(v). These are outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the supervisory practitioner's immediate availability to furnish assistance and direction after the initiation of the service, and that are not primarily surgical in nature. In the provision of these services, CMS requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision for the remainder of the service at the discretion of the supervisory practitioner. The CMS OPPS Website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html includes a table listing the current extended duration services for the payment year.

For these services, direct supervision means the definition specified for all outpatient therapeutic services in 410.27(a)(1)(iv), that is, immediate availability to furnish assistance and direction throughout the performance of the procedure. General supervision means the definition specified in the physician fee schedule at 410.32(b)(3)(i), that the service is performed under the supervisory practitioner's overall direction and control but his or her presence is not required during the performance of the procedure.

"Initiation" means the beginning portion of the extended duration service, ending when the supervisory practitioner believes the patient is stable enough for the remainder of the service to be safely administered under general supervision. The point of transition to general supervision must be documented in the patient's progress notes or medical record. The manner of documentation is otherwise at the discretion of each supervisory practitioner.