

Medicare Benefit Policy Manual

Chapter 6 - Hospital Services Covered Under Part B

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10 - Medical and Other Health Services Furnished to Inpatients of Participating Hospitals

(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)

Payment may be made under Part B for physician services and for the nonphysician medical and other health services as provided in this section when furnished by a participating hospital (either directly or under arrangements) to an inpatient of the hospital, but only if payment for these services cannot be made under Part A. This policy applies to all hospitals and critical access hospitals (CAHs) participating in Medicare, including those paid under a prospective payment system or alternative payment methodology such as State cost control systems, and to emergency hospital services furnished by nonparticipating hospitals. In this section, the term “hospital” includes all hospitals and CAHs, regardless of payment methodology, unless otherwise specified.

For services to be covered under Part A or Part B, a hospital must furnish nonphysician services to its inpatients directly or under arrangements (see chapter 16, §170 of this manual, “Inpatient Hospital or SNF Services Not Delivered Directly or Under Arrangement by the Provider”). A nonphysician service is one which does not meet the criteria defining physicians’ services specifically provided for in regulation at 42 CFR 415.102. Services “incident to” physicians’ services (except for the services of nurse anesthetists employed by anesthesiologists) are nonphysician services for purposes of this provision.

10.1 - Reasonable and Necessary Part A Hospital Inpatient Claim Denials

(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)

If a Medicare Part A claim for inpatient hospital services is denied because the inpatient admission was not reasonable and necessary, or if a hospital determines under 42 CFR §482.30(d) or §485.641 after a beneficiary is discharged that the beneficiary’s inpatient admission was not reasonable and necessary, and if waiver of liability payment is not made, the hospital may be paid for the following Part B inpatient services that would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient rather than admitted as an inpatient, provided the beneficiary is enrolled in Medicare Part B:

- 1) Part B services paid under the outpatient prospective payment system (OPPS), excluding observation services and hospital outpatient visits that require an outpatient status. Hospitals that are excluded from payment under the OPPS are instead paid under their alternative payment methodology (e.g., reasonable cost, all inclusive rate, or Maryland waiver) for the services that are otherwise payable under the OPPS.
- 2) The following services excluded from OPPS payment, that are instead paid under the respective Part B fee schedules or prospectively determined rates for which payment is made for these services when provided to hospital outpatients:

- a. Physical therapy services, speech-language pathology services, and occupational therapy services (see chapter 15, §§220 and 230 of this manual, “Covered Medical and Other Health Services,”).
- b. Ambulance services.
- c. Prosthetic devices, prosthetic supplies, and orthotic devices paid under the DMEPOS fee schedule (excludes implantable prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care) and replacement of such devices).
- d. Durable medical equipment supplied by the hospital for the patient to take home, except durable medical equipment that is implantable.
- e. Certain clinical diagnostic laboratory services.
- f. Screening and diagnostic mammography services.
- g. Annual wellness visit providing personalized prevention plan services.

Hospitals may also be paid under Part B for services included in the payment window prior to the point of inpatient admission for outpatient services treated as inpatient services (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §10.12, “Payment Window for Outpatient Services Treated as Inpatient Services”), including services requiring an outpatient status. The hospital can only bill for services that it provided directly or under arrangement in accordance with Part B payment rules. Outpatient therapeutic services furnished at an entity that is wholly owned or wholly operated by the hospital and is not part of the hospital (such as a physician’s office), may not be billed by the hospital to Part B. Reference labs may be billed only if the referring laboratory does not bill for the laboratory test (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, §40.1, “Laboratories Billing for Referred Tests”).

The services billed to Part B must be reasonable and necessary and must meet all applicable Part B coverage and payment conditions. Claims for Part B services submitted following a reasonable and necessary Part A claim denial or hospital utilization review determination must be filed no later than the close of the period ending 12 months or 1 calendar year after the date of service (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, §70 “Time Limitations for Filing Part A and Part B Claims”). See Pub. 100-04, Medicare Claims Processing Manual, chapter 4, §240 for required bill types.

10.2 - Other Circumstances in Which Payment Cannot Be Made Under Part A

(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)

Part B payment could be made to a hospital for the medical and other health services listed in this section for inpatients enrolled in Part B if:

- No Part A prospective payment is made at all for the hospital stay because of patient exhaustion of benefit days before or during the admission; or
- The patient was not otherwise eligible for or entitled to coverage under Part A (see chapter 16, §180 of this manual for services received as a result of non-covered services).

Beginning in 2014, for hospitals paid under the OPPS these Part B inpatient services are separately payable under Part B, and are excluded from OPPS packaging if the primary service with which the service would otherwise be bundled is not a payable Part B inpatient service.

The following inpatient services are payable under the OPPS:

- Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;
- Acute dialysis of a hospital inpatient with or without end stage renal disease (ESRD). The charge for hemodialysis is a charge for the use of a prosthetic device, billed in accordance with Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §200.2, “Hospital Dialysis Services for Patients With and Without End Stage Renal Disease (ESRD).”
- Screening pap smears;
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines;
- Colorectal screening;
- Bone mass measurements;
- Prostate screening;
- Hemophilia clotting factors for hemophilia patients competent to use these factors without supervision;
- Immunosuppressive drugs;
- Oral anti-cancer drugs;

- Oral drug prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen; and
- Epoetin Alfa (EPO) that is not covered under the ESRD benefit.

The following inpatient services are payable under the non-OPPS Part B fee schedules or prospectively determined rates listed:

- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations (DMEPOS fee schedule);
- Prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of intraocular lens (DMEPOS fee schedule, except for implantable prosthetic devices paid at the applicable rate under Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §240.3, “Inpatient Part B Hospital Services - Implantable Prosthetic Devices”);
- Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes including replacements if required because of a change in the patient’s physical condition (DMEPOS fee schedule);
- Physical therapy services, speech-language pathology services, and occupational therapy services (see Chapter 15, §§220 and 230 of this manual, “Covered Medical and Other Health Services”) (applicable rate based on the Medicare Physician Fee Schedule);
- Ambulance services (ambulance fee schedule); and
- Screening mammography services (Medicare Physician Fee Schedule).

Hospitals may also be paid under Part B for services included in the payment window prior to the point of inpatient admission for outpatient services treated as inpatient services (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 4, §10.12, “Payment Window for Outpatient Services Treated as Inpatient Services”), including services requiring an outpatient status. The hospital can only bill for services that it provided directly or under arrangement in accordance with Part B payment rules. Outpatient therapeutic services furnished at an entity that is wholly owned or wholly operated by the hospital and is not part of the hospital (such as a physician’s office), may not be billed by the hospital to Part B. Reference labs may be billed only if the referring laboratory does not bill for the laboratory test (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 16, §40.1, “Laboratories Billing for Referred Tests”).

The services billed to Part B must be reasonable and necessary and must meet all applicable Part B coverage and payment conditions. Claims for these services must be filed no later than the close of the period ending 12 months or 1 calendar year after the date of service (see Pub. 100-04, Medicare Claims Processing Manual, Chapter 1, §70, “Time Limitations for Filing Part A and Part B Claims”). See Pub. 100-04, Medicare Claims Processing Manual, chapter 4, §240 for required bill types.

10.3 - Hospital Inpatient Services Paid Only Under Part B **(Rev. 182, Issued: 03-21-14, Effective: 10-01-13, Implementation: 04-21-14)**

The services listed in Chapter 15, §250 of this manual, “Medical and Other Health Services Furnished to Inpatients of Hospitals and Skilled Nursing Facilities,” when provided to a hospital inpatient, may be covered under Part B, even though the patient has Part A coverage for the hospital stay. This is because these services are covered under Part B and are not covered under Part A.

In all hospitals, all other services provided to a hospital inpatient must be treated as an inpatient hospital service to be paid for under Part A, if Part A coverage is available and the beneficiary is entitled to Part A. This is because every hospital must provide directly or arrange for any nonphysician service rendered to its inpatients, and a hospital can be paid under Part B for a service provided in this manner only if Part A coverage does not exist.

However, note that in order to have any Medicare coverage at all (Part A or Part B), any nonphysician service rendered to a hospital inpatient must be provided directly or arranged for by the hospital.

20 - Outpatient Hospital Services **(Rev. 157, Issued: 06-08-12, Effective: 07-01-12, Implementation: 07-02-12)**

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

(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

(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:

- Physicians' 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 §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

(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

(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

(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.

20.4.2 - Reserved

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

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

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

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

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

1. They are furnished by the hospital or under arrangements made by the hospital or CAH with another entity (see section 20.1 of this chapter);
2. They are ordinarily furnished by, or under arrangements made by the hospital or CAH to its outpatients for the purpose of diagnostic study;
3. They would be covered as inpatient hospital services if furnished to an inpatient; and
4. Payment is allowed under the hospital outpatient prospective payment system for diagnostic services furnished at a facility that is designated as provider-based only when those services are furnished under the appropriate level of supervision specified in accordance with the definitions at 42 CFR 410.32(b)(3)(i), (b)(3)(ii), and (b)(3)(iii), and as described in Chapter 15 of this manual, Section 80 "Requirements for Diagnostic X-ray, Diagnostic Laboratory, and Other Diagnostic Tests," as though they are being furnished in a physician's office or clinic setting. With respect to individual diagnostic tests, the supervision levels listed in the quarterly updated Medicare Physician Fee Schedule (MPFS) Relative Value File apply. For diagnostic services not listed in the MPFS, Medicare contractors, in consultation with their medical directors, define appropriate supervision levels in order to determine whether claims for these services are reasonable and necessary.

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

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

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

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

(Rev. 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.

20.4.5 - 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 - Outpatient Therapeutic Services (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 (Rev. 128, Issued: 05-28-10, Effective: 07-01-10, Implementation: 07-06-10)

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

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

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

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

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

Services," Sections 220 and 230, for outpatient physical therapy and speech-language pathology coverage conditions.

20.5.2 - Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or After January 1, 2010
(Rev. 169, Issued: 03- 01- 13, Effective: 04-01-13, Implementation: 04- 01-13)

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.

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 OPPTS 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)**

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.

30 - Drugs and Biologicals **(Rev. 1, 10-01-03)** **A3-3112.4.B, HO-230.4.B**

See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §50 for a description of conditions for coverage for drugs and biologicals.

Notwithstanding the instructions in the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” drugs and biologicals furnished to hospital or SNF inpatients who have exhausted Part A benefits, or who are not eligible under Part A, are not covered under Part B except the following:

- Hemophilia clotting factors (The limitation contained in 42 CFR 410.10(q) states that this applies to hemophilia patients competent to use these factors without supervision);
- Immunosuppressive drugs;
- Oral anti-cancer drugs;
- Oral drug prescribed for use as an acute anti-emetic used as part of an anti-cancer chemotherapeutic regimen; or
- Epoetin Alfa (EPO).

Specific coverage for each of the above drugs is found in Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §§50.

In addition pneumococcal pneumonia, influenza virus, and hepatitis B vaccines are covered under Part B. See the Medicare Claims Processing Manual, Chapter 18, “Preventive and Screening Services,” and the Medicare Benefit Policy Manual, Chapter 15, for additional information concerning these vaccines.

40 - Other Covered Services and Items

(Rev. 1, 10-01-03)

A3-3112.4.C, HO-230.4.D

Covered services and items provided by the hospital in connection with a clinic visit or a physician’s treatment of outpatients include the use of the following:

- Hospital facilities, including the use of the emergency room;
- Services of nurses, nonphysician anesthetists, psychologists, technicians, therapists, and other aides; and
- Medical supplies such as gauze, oxygen, ointments, and other supplies used by physicians or hospital personnel in the treatment of outpatients.

Additional examples of covered items are surgical dressings; splints, casts, and other devices used for reduction of fractures and dislocations; prosthetic devices; leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes.

50 - Sleep Disorder Clinics

(Rev. 1, 10-01-03)

A3-3112.5

Sleep disorder clinics are facilities in which certain conditions are diagnosed through the study of sleep. Such clinics are for diagnosis, therapy, and research. Sleep disorder clinics may provide some diagnostic or therapeutic services that are covered under Medicare. These clinics may be affiliated either with a hospital or a freestanding facility. Whether a clinic is hospital-affiliated or freestanding, coverage for diagnostic services under some circumstances is covered under provisions of the law different from those for coverage of therapeutic services.

60 - Intermittent Peritoneal Dialysis Services

(Rev. 1, 10-01-03)

A3-3112.6

See the discussion of dialysis services in the Medicare Benefits Policy Manual, Chapter 11, “End Stage Renal Disease.”

70 - Outpatient Hospital Psychiatric Services

(Rev. 1, 10-01-03)

A3-3112.7, HO-230.5

70.1 - General

(Rev. 10, 05-07-04)

A3-3112.7.A, HO-230.5.A

There is a wide range of services and programs that a hospital may provide to its outpatients who need psychiatric care, ranging from a few individual services to comprehensive, full-day programs; from intensive treatment programs to those that provide primarily supportive.

In general, to be covered the services must be:

- Incident to a physician’s service (see §20.4); and
- Reasonable and necessary for the diagnosis or treatment of the patient’s condition.

This means the services must be for the purpose of diagnostic study or the services must reasonably be expected to improve the patient’s condition.

A. Coverage Criteria

The services must meet the following criteria:

1. Individualized Treatment Plan

Services must be prescribed by a physician and provided under an individualized written plan of treatment established by a physician after any needed consultation with appropriate staff members. The plan must state the type, amount, frequency, and duration of the services to be furnished and indicate the diagnoses and anticipated goals. (A plan is not required if only a few brief services are furnished.)

2. Physician Supervision and Evaluation

Services must be supervised and periodically evaluated by a physician to determine the extent to which treatment goals are being realized. The evaluation must be based on periodic consultation and conference with therapists and staff, review of medical records, and patient interviews. Physician entries in medical records must support this involvement. The physician must also provide supervision and direction to any therapist involved in the patient's treatment and see the patient periodically to evaluate the course of treatment and to determine the extent to which treatment goals are being realized and whether changes in direction or emphasis are needed.

3. Reasonable Expectation of Improvement

Services must be for the purpose of diagnostic study or reasonably be expected to improve the patient's condition. The treatment must, at a minimum, be designed to reduce or control the patient's psychiatric symptoms so as to prevent relapse or hospitalization, and improve or maintain the patient's level of functioning.

It is not necessary that a course of therapy have as its goal restoration of the patient to the level of functioning exhibited prior to the onset of the illness, although this may be appropriate for some patients. For many other psychiatric patients, particularly those with long-term, chronic conditions, control of symptoms and maintenance of a functional level to avoid further deterioration or hospitalization is an acceptable expectation of improvement. "Improvement" in this context is measured by comparing the effect of continuing treatment versus discontinuing it. Where there is a reasonable expectation that if treatment services were withdrawn the patient's condition would deteriorate, relapse further, or require hospitalization, this criterion is met.

Some patients may undergo a course of treatment that increases their level of functioning, but then reach a point where further significant increase is not expected. Such claims are not automatically considered noncovered because conditions have stabilized, or because treatment is now primarily for the purpose of maintaining present level of functioning. Rather, coverage depends on whether the criteria discussed above are met. Services are noncovered only where the evidence clearly establishes that the criteria are not met; for example, that stability can be maintained without further treatment or with less intensive treatment.

B. Partial Hospitalization

Partial hospitalization is a distinct and organized intensive treatment program for patients who would otherwise require inpatient psychiatric care. See §70.3 for specific program requirements.

C. Application of Criteria

The following discussion illustrates the application of the above guidelines to the more common modalities and procedures used in the treatment of psychiatric patients and some factors that are considered in determining whether the coverage criteria are met.

1. Covered Services

Services generally covered for the treatment of psychiatric patients are:

- Individual and group therapy with physicians, psychologists, or other mental health professionals authorized by the State.
- Occupational therapy services are covered if they require the skills of a qualified occupational therapist and be performed by or under the supervision of a qualified occupational therapist or by an occupational therapy assistant.
- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.
- Drugs and biologicals furnished to outpatients for therapeutic purposes, but only if they are of a type which cannot be self-administered.
- Activity therapies but only those that are individualized and essential for the treatment of the patient's condition. The treatment plan must clearly justify the need for each particular therapy utilized and explain how it fits into the patient's treatment.
- Family counseling services. Counseling services with members of the household are covered only where the primary purpose of such counseling is the treatment of the patient's condition.
- Patient education programs, but only where the educational activities are closely related to the care and treatment of the patient.
- Diagnostic services for the purpose of diagnosing those individuals for whom an extended or direct observation is necessary to determine functioning and interactions, to identify problem areas, and to formulate a treatment plan.

2. Noncovered Services

The following are generally not covered except as indicated:

- Meals and transportation.
- Activity therapies, group activities or other services and programs which are primarily recreational or diversional in nature. Outpatient psychiatric day treatment programs that consist entirely of activity therapies are not covered.

"Geriatric day care" programs are available in both medical and nonmedical settings. They provide social and recreational activities to older individuals who need some supervision during the day while other family members are away from home. Such programs are not covered since they are not considered reasonable and necessary for a diagnosed psychiatric disorder, nor do such programs routinely have physician involvement.

- Psychosocial programs. These are generally community support groups in nonmedical settings for chronically mentally ill persons for the purpose of social interaction. Outpatient programs may include some psychosocial components; and to the extent these components are not primarily for social or recreational purposes, they are covered. However, if an individual's outpatient hospital program consists entirely of psychosocial activities, it is not covered.
- Vocational training. While occupational therapy may include vocational and prevocational assessment and training, when the services are related solely to specific employment opportunities, work skills or work settings, they are not covered.

3. Frequency and Duration of Services

There are no specific limits on the length of time that services may be covered. There are many factors that affect the outcome of treatment; among them are the nature of the illness, prior history, the goals of treatment, and the patient's response. As long as the evidence shows that the patient continues to show improvement in accordance with his/her individualized treatment plan, and the frequency of services is within accepted norms of medical practice, coverage may be continued.

If a patient reaches a point in his/her treatment where further improvement does not appear to be indicated, evaluate the case in terms of the criteria to determine whether with continued treatment there is a reasonable expectation of improvement.

70.2 - Coverage Criteria for Outpatient Hospital Psychiatric Services (Rev. 1, 10-01-03) A3-3112.7.B, HO-235.5.B

The services must meet the criteria outlined in the National Coverage Determinations Manual.

70.3 - Partial Hospitalization Services

(Rev. 194, Issued: 09-03-14, Effective: Upon Implementation of ICD-10, Implementation: Upon Implementation of ICD-10)

Partial hospitalization programs (PHPs) are structured to provide intensive psychiatric care through active treatment that utilizes a combination of the clinically recognized items and services described in §1861(ff) of the Social Security Act (the Act). The treatment program of a PHP closely resembles that of a highly structured, short-term hospital inpatient program. It is treatment at a level more intense than outpatient day treatment or psychosocial rehabilitation. Programs providing primarily social, recreational, or diversionary activities are not considered partial hospitalization.

A. Program Criteria

PHPs work best as part of a community continuum of mental health services which range from the most restrictive inpatient hospital setting to less restrictive outpatient care and support. Program objectives should focus on ensuring important community ties and closely resemble the real-life experiences of the patients served. PHPs may be covered under Medicare when they are provided by a hospital outpatient department or a Medicare-certified CMHC.

Partial hospitalization is active treatment that incorporates an individualized treatment plan which describes a coordination of services wrapped around the particular needs of the patient, and includes a multidisciplinary team approach to patient care under the direction of a physician. The program reflects a high degree of structure and scheduling. According to current practice guidelines, the treatment goals should be measurable, functional, time-framed, medically necessary, and directly related to the reason for admission.

A program comprised primarily of diversionary activity, social, or recreational therapy does not constitute a PHP. Psychosocial programs which provide only a structured environment, socialization, and/or vocational rehabilitation are not covered by Medicare. A program that only monitors the management of medication for patients whose psychiatric condition is otherwise stable, is not the combination, structure, and intensity of services which make up active treatment in a PHP.

B. Patient Eligibility Criteria

1. Benefit Category

Patients must meet benefit requirements for receiving the partial hospitalization services as defined in §1861(ff) and §1835(a)(2)(F) of the Act. Patients admitted to a PHP must be under the care of a physician who certifies the need for partial hospitalization and require a minimum of 20 hours per week of therapeutic services, as evidenced by their plan of care. The patients also require a comprehensive, structured, multimodal treatment requiring medical supervision and coordination, provided under an individualized plan of

care, because of a mental disorder which severely interferes with multiple areas of daily life, including social, vocational, and/or educational functioning. Such dysfunction generally is of an acute nature. In addition, PHP patients must be able to cognitively and emotionally participate in the active treatment process, and be capable of tolerating the intensity of a PHP program.

Patients meeting benefit category requirements for Medicare coverage of a PHP comprise two groups: those patients who are discharged from an inpatient hospital treatment program, and the PHP is in lieu of continued inpatient treatment; or those patients who, in the absence of partial hospitalization, would be at reasonable risk of requiring inpatient hospitalization. Where partial hospitalization is used to shorten an inpatient stay and transition the patient to a less intense level of care, there must be evidence of the need for the acute, intense, structured combination of services provided by a PHP. Recertification must address the continuing serious nature of the patients' psychiatric condition requiring active treatment in a PHP.

Discharge planning from a PHP may reflect the types of best practices recognized by professional and advocacy organizations that ensure coordination of needed services and follow-up care. These activities include linkages with community resources, supports, and providers in order to promote a patient's return to a higher level of functioning in the least restrictive environment.

2. Covered Services

Items and services that can be included as part of the structured, multimodal active treatment program, identified in §1861(ff)(2) include:

- Individual or group psychotherapy with physicians, psychologists, or other mental health professionals authorized or licensed by the State in which they practice (e.g., licensed clinical social workers, clinical nurse specialists, certified alcohol and drug counselors);
- Occupational therapy requiring the skills of a qualified occupational therapist. Occupational therapy, if required, must be a component of the physicians treatment plan for the individual;
- Services of other staff (social workers, psychiatric nurses, and others) trained to work with psychiatric patients;
- Drugs and biologicals that cannot be self administered and are furnished for therapeutic purposes (subject to limitations specified in 42 CFR 410.29);
- Individualized activity therapies that are not primarily recreational or diversionary. These activities must be individualized and essential for the treatment of the patient's diagnosed condition and for progress toward treatment goals;

- Family counseling services for which the primary purpose is the treatment of the patient's condition;
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment of his/her diagnosed psychiatric condition; and
- Medically necessary diagnostic services related to mental health treatment.

Partial hospitalization services that make up a program of active treatment must be vigorous and proactive (as evidenced in the individual treatment plan and progress notes) as opposed to passive and custodial. It is not enough that a patient qualify under the benefit category requirements in or of §1835(a)(2)(F) unless he/she also has the need for the active treatment provided by the program of services defined in §1861(ff). It is the need for intensive, active treatment of his/her condition to maintain a functional level and to prevent relapse or hospitalization, which qualifies the patient to receive the services identified in §1861(ff).

3. Reasonable and Necessary Services

This program of services provides for the diagnosis and active, intensive treatment of the individual's serious psychiatric condition and, in combination, are reasonably expected to improve or maintain the individual's condition and functional level and prevent relapse or hospitalization. A particular individual covered service (described above) as intervention, expected to maintain or improve the individual's condition and prevent relapse, may also be included within the plan of care, but the overall intent of the partial program admission is to treat the serious presenting psychiatric symptoms. Continued treatment in order to maintain a stable psychiatric condition or functional level requires evidence that less intensive treatment options (e.g., intensive outpatient, psychosocial, day treatment, and/or other community supports) cannot provide the level of support necessary to maintain the patient and to prevent hospitalization.

Patients admitted to a PHP do not require 24 hour per day supervision as provided in an inpatient setting, must have an adequate support system to sustain/maintain themselves outside the PHP and must not be an imminent danger to themselves or others. Patients admitted to a PHP generally have an acute onset or decompensation of a covered Axis I mental disorder, as defined by the current edition of the Diagnostic and Statistical Manual published by the American Psychiatric Association or listed in Chapter 5, of the version of the International Classification of Diseases (ICD) applicable to the service date, which severely interferes with multiple areas of daily life. The degree of impairment will be severe enough to require a multidisciplinary intensive, structured program, but not so limiting that patients cannot benefit from participating in an active treatment program. It is the need, as certified by the treating physician, for the intensive, structured combination of services provided by the program that constitute active treatment, that are necessary to appropriately treat the patient's presenting psychiatric condition.

For patients who do not meet this degree of severity of illness, and for whom partial hospitalization services are not necessary for the treatment of a psychiatric condition, professional services billed to Medicare Part B (e.g., services of psychiatrists and psychologists) may be medically necessary, even though partial hospitalization services are not.

Patients in PHP may be discharged by either stepping up to an inpatient level of care which would be required for patients needing 24-hour supervision, or stepping down to a less intensive level of outpatient care when the patient's clinical condition improves or stabilizes and he/she no longer requires structured, intensive, multimodal treatment.

4. Reasons for Denial

a. Benefit category denials made under §1861(ff) or §1835(a)(2)(F) are not appealable by the provider and the limitation on liability provision does not apply (HCFA Ruling 97-1). Examples of benefit category based in §1861(ff) or §1835(a)(2)(F) of the Act, for partial hospitalization services generally include the following:

- Day care programs, which provide primarily social, recreational, or diversionary activities, custodial or respite care;
- Programs attempting to maintain psychiatric wellness, where there is no risk of relapse or hospitalization, e.g., day care programs for the chronically mentally ill; or
- Patients who are otherwise psychiatrically stable or require medication management only.

b. Coverage denials made under §1861(ff) of the Act are not appealable by the provider and the Limitation on Liability provision does not apply (HCFA Ruling 97-1). The following services are excluded from the scope of partial hospitalization services defined in §1861(ff) of the Social Security Act:

- Services to hospital inpatients;
- Meals, self-administered medications, transportation; and
- Vocational training.

c. Reasonable and necessary denials based on §1862(a)(1)(A) are appealable and the Limitation on Liability provision does apply. The following examples represent reasonable and necessary denials for partial hospitalization services and coverage is excluded under §1862(a)(1)(A) of the Social Security Act:

- Patients who cannot, or refuse, to participate (due to their behavioral or cognitive status) with active treatment of their mental disorder (except for a

brief admission necessary for diagnostic purposes), or who cannot tolerate the intensity of a PHP; or

- Treatment of chronic conditions without acute exacerbation of symptoms that place the individual at risk of relapse or hospitalization.

5. Documentation Requirements and Physician Supervision

The following components will be used to help determine whether the services provided were accurate and appropriate.

a. Initial Psychiatric Evaluation/Certification.--Upon admission, a certification by the physician must be made that the patient admitted to the PHP would require inpatient psychiatric hospitalization if the partial hospitalization services were not provided. The certification should identify the diagnosis and psychiatric need for the partial hospitalization. Partial hospitalization services must be furnished under an individualized written plan of care, established by the physician, which includes the active treatment provided through the combination of structured, intensive services identified in §1861 that are reasonable and necessary to treat the presentation of serious psychiatric symptoms and to prevent relapse or hospitalization.

b. Physician Recertification Requirements.--

- Signature – The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.
- Timing – The first recertification is required as of the 18th calendar day following admission to the PHP. Subsequent recertifications are required at intervals established by the provider, but no less frequently than every 30 days.
- Content – The recertification must specify that the patient would otherwise require inpatient psychiatric care in the absence of continued stay in the PHP and describe the following:
 - The patient's response to the therapeutic interventions provided by the PHP;
 - The patient's psychiatric symptoms that continue to place the patient at risk of hospitalization; and
 - Treatment goals for coordination of services to facilitate discharge from the PHP.

c. Treatment Plan.--Partial hospitalization is active treatment pursuant to an individualized treatment plan, prescribed and signed by a physician, which identifies

treatment goals, describes a coordination of services, is structured to meet the particular needs of the patient, and includes a multidisciplinary team approach to patient care. The treatment goals described in the treatment plan should directly address the presenting symptoms and are the basis for evaluating the patient's response to treatment. Treatment goals should be designed to measure the patient's response to active treatment. The plan should document ongoing efforts to restore the individual patient to a higher level of functioning that would permit discharge from the program, or reflect the continued need for the intensity of the active therapy to maintain the individual's condition and functional level and to prevent relapse or hospitalization. Activities that are primarily recreational and diversionary, or provide only a level of functional support that does not treat the serious presenting psychiatric symptoms placing the patient at risk, do not qualify as partial hospitalization services.

d. Progress Notes.--Section 1833(e) of the Social Security Act prevents Medicare from paying for services unless necessary and sufficient information is submitted that shows that services were provided and to determine the amounts due. A provider may submit progress notes to document the services that have been provided. The progress note should include a description of the nature of the treatment service, the patient's response to the therapeutic intervention and its relation to the goals indicated in the treatment plan.

See the Medicare Claims Processing Manual, Chapter 4, "Hospital Outpatient Services," §260 for billing instructions for partial hospitalization services.

70.5 - Laboratory Services Furnished to Nonhospital Patients by Hospital Laboratory

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

A nonhospital patient is an individual who is neither an inpatient nor outpatient of the hospital furnishing the service. (See the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 1, "Inpatient Hospital Services," section 10, for the definition of a hospital inpatient and section 20.1 for the definition of a hospital outpatient). Nonhospital patients primarily are individuals from whom a specimen had been taken and sent to the hospital for analysis and the patient does not receive hospital outpatient services on the same day. For all hospitals except CAHs and Maryland waiver hospitals, if a beneficiary receives hospital outpatient services on the same day as a specimen collection and laboratory test, then the patient is considered to be a registered hospital outpatient and cannot be considered to be a non-patient on that day for purposes of the specimen collection and laboratory test. However if the non-CAH or Maryland waiver hospital only collects or draws a specimen from the beneficiary and the beneficiary does not also receive hospital outpatient services on that day, the hospital may choose to register the beneficiary as an outpatient for the specimen collection or bill for these services as non-patient on the 14X bill type.

For CAHs, payment for clinical diagnostic laboratory tests is made at 101 percent of reasonable cost, only if the individuals are outpatients of the CAH, as defined in 42 CFR

410.2, and are physically present in the CAH at the time the specimens are collected. Clinical diagnostic laboratory tests performed for persons who are not physically present (non-patients) at the CAH when the specimens are collected are made in accordance with the provisions of sections 1833(a)(1)(D) and 1833(a)(2)(D) of the Social Security Act. See also 42 CFR 413.70(b)(iii). Similarly, for Maryland waiver hospitals, the waiver is limited to services to inpatients and registered outpatients as defined in 42 CFR 410.2. Therefore payment for non-patients (specimen only, TOB 14X) who are not registered outpatients at the time of specimen collection will be made on the clinical diagnostic laboratory fee schedule. Such services are covered to the extent appropriate.

See the Medicare Claims Processing Manual, Pub. 100-04, Chapter 16, "Laboratory Services from Independent Labs, Physicians, and Providers," section 40.3, for billing and payment of clinical diagnostic laboratory services for patients and non-patients.

80 - Rental and Purchase of Durable Medical Equipment

(Rev. 1, 10-01-03)

A3-3113, HO-235, HHA-220

Rental and purchase of DME is covered under Part B for use in a patient's home. DME rendered to inpatients of a SNF or hospital is covered as part of the prospective payment system and not separately payable. See the Medicare Benefit Policy Manual, Chapter 15, §§110 for coverage of Durable Medical Equipment and the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for special billing instructions.

90 - Services of Interns And Residents

(Rev. 1, 10-01-03)

A3-3115, HO-237

A. General

For Medicare purposes, the terms "interns" and "residents" include physicians participating in approved postgraduate training programs and physicians who are not in approved programs but who are authorized to practice only in a hospital setting, e.g., individuals with temporary or restricted licenses, or unlicensed graduates of foreign medical schools. Where a senior resident has a staff or faculty appointment or is designated, for example, a "fellow," it **does not** change the resident's status for the purposes of Medicare coverage and reimbursement. As a general rule, services of interns and residents are paid as provider services by the intermediary.

B. Services Furnished by Interns and Residents Within the Scope of an Approved Training Program

Medical and surgical services furnished by interns and residents within the scope of their training program are covered as provider services. Effective with services furnished on or after July 1, 1987, this includes services furnished in a setting which is not part of the

provider where a hospital has agreed to incur all or substantially all of the costs of training in the nonprovider facility. Providers are required to notify the Medicare carrier of such agreements. Where the provider does not incur all or substantially all of the training costs and the services are performed by a licensed physician, the services are reimbursable on a reasonable charge basis by the carrier. Prior to July 1, 1987, the covered services of interns and residents were reimbursed by the carrier on a reasonable charge basis as physician services if furnished by a licensed physician off the provider premises regardless of who incurred the training costs.

C. Services Furnished by Interns and Residents Outside the Scope of an Approved Training Program - Moonlighting

Medical and surgical services furnished by interns and residents that are not related to their training program, and are performed outside the facility where they have their training program, are covered as physicians' services and paid on a reasonable charge basis where the requirements in 1 and 2, below, are met. Medical and surgical services furnished by interns and residents that are not related to their training program, and are performed in an outpatient department or emergency room of the hospital where they have their training program, are covered as physicians' services and paid on a reasonable charge basis where the following criteria are met:

1. The services are identifiable physicians' services, the nature of which requires performance by a physician in person and which contributes to the diagnosis or treatment of the patient's condition;
2. The intern or resident is fully licensed to practice medicine, osteopathy, dentistry or podiatry by the State in which the services are performed; and
3. The services performed can be separately identified from those services that are required as part of the training program.

When these criteria are met, the services are considered to have been furnished by the individuals in their capacity as physicians and not in their capacity as interns and residents.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R215BP</u>	12/18/2015	January 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/04/2016	9486
<u>R194BP</u>	09/03/2014	Pub. 100-02 Language-Only Update for ICD-10	Upon Implementation of ICD-10	8605
<u>R182BP</u>	03/21/2014	Implementing the Part B Inpatient Payment Policies from CMS-1599-F	04/21/2014	8666
<u>R181BP</u>	03/14/2014	Pub. 100-02 Language-Only Update for ICD-10 – Rescinded and replaced by Transmittal 194	10/01/2014	8605
<u>R169BP</u>	03/01/2013	April 2013 Update of the Hospital Outpatient Prospective Payment System (OPPS)	04/01/2013	8228
<u>R157BP</u>	06-08-2012	July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/02/2012	7847
<u>R152BP</u>	12/29/2011	January 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/03/2012	7672
<u>R143BP</u>	04/29/2011	Manual Restructuring of Chapter 6, Section 20, Subsections 20.4.4 and 20.5.2	05/31/2011	7354
<u>R137BP</u>	12/30/2010	January 2011 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/03/2011	7271
<u>R128BP</u>	05/28/2010	July 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/06/2010	6996
<u>R116BP</u>	12/11/2009	January 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/04/2010	6751

<u>R107BP</u>	05/22/2009	July 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/06/2009	6492
<u>R101BP</u>	01/16/2009	January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/05/2009	6320
<u>R100BP</u>	12/31/2008	January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS) – Rescinded and replaced by Transmittal 101	01/05/2009	6320
<u>R90BP</u>	06/19/2008	July Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/07/2008	6094
<u>R82BP</u>	02/08/2008	January 2008 Update of the Hospital Outpatient Prospective Payment System (OPPS) Manualization	03/10/2008	5946
<u>R42BP</u>	12/16/2005	January 2006 Update of the Hospital Outpatient Prospective Payment System (OPPS) Manual Instruction: Changes to Coding and Payment for Observation	01/03/2006	4259
<u>R37BP</u>	08/12/2005	Conforming Changes for Change Request 3648 to Pub. 100-02	09/12/2005	3912
<u>R19BP</u>	09/10/2004	Hospital Services Covered Under Part B	10/12/2004	3444
<u>R10BP</u>	05/07/2004	Chapter 6, Hospital Services Covered Under Part B	N/A	3298
<u>R1BP</u>	10/01/2003	Introduction to the Benefit Policy Manual	N/A	N/A

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