Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

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(Rev. 157, 06-08-12)

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10 - Supplementary Medical Insurance (SMI) Provisions
(Rev. 37, Issued: 08-12-05; Effective/Implementation: 09-12-05)

The supplementary medical insurance plan covers expenses incurred for the following medical and other health services under Part B of Medicare:

- Physician's services, including surgery, consultation, office and institutional calls, and services and supplies furnished incident to a physician's professional service;
- Outpatient hospital services furnished incident to physicians services;
- Outpatient diagnostic services furnished by a hospital;
- Outpatient physical therapy, outpatient occupational therapy, outpatient speech-language pathology services;
- Diagnostic x-ray tests, laboratory tests, and other diagnostic tests;
- X-ray, radium, and radioactive isotope therapy;
- Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;
- Rental or purchase of durable medical equipment for use in the patient's home;
- Ambulance service;
- Prosthetic devices, other than dental, which replace all or part of an internal body organ;
- Leg, arm, back and neck braces and artificial legs, arms, and eyes including adjustments, repairs, and replacements required because of breakage, wear, loss, or change in the patient's physical condition;
- Certain medical supplies used in connection with home dialysis delivery systems;
- Rural health clinic (RHC) services;
- Federally Qualified Health Center (FQHC) services;
- Ambulatory surgical center (ASC) services;
- Screening mammography services;
- Screening pap smears and pelvic exams;

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- Screening glaucoma services;
- Influenza, pneumococcal pneumonia, and hepatitis B vaccines;
- Colorectal screening;
- Bone mass measurements;
- Diabetes self-management services;
- Prostate screening; and
- Home health visits after all covered Part A visits have been used.

See §250 for provisions regarding supplementary medical insurance coverage of certain of these services when furnished to hospital and SNF inpatients.

Payment may not be made under Part B for services furnished an individual if the individual is entitled to have payment made for those services under Part A. An individual is considered entitled to have payment made under Part A if the expenses incurred were used to satisfy a Part A deductible or coinsurance amount, or if payment would be made under Part A except for the lack of a request for payment or lack of a physician certification.

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Some medical services may be considered for coverage under more than one of the above-enumerated categories. For example, electrocardiograms (EKGs) can be covered as physician's services or as other diagnostic tests. It is sufficient to determine that the requirements for coverage under one category are met to permit payment.

Membership dues, subscription fees, charges for service policies, insurance premiums, and other payments analogous to premiums which entitle enrollees to services or to repairs or replacement of devices or equipment or parts thereof without charge or at a reduced charge, are not considered expenses incurred for covered items or services furnished under such contracts or undertakings. Examples of such arrangements are memberships in ambulance companies, insurance for replacement of prosthetic lenses, and service contracts for durable medical equipment.

20 - When Part B Expenses Are Incurred

(Rev. 1, 10-01-03)
B3-2005

Part B expenses for items and services other than expenses for surgery and childbirth (see §20.1, below), are considered to have been incurred on the date the beneficiary received the item or service, regardless of when it was paid for or ordered. Therefore, when an individual orders an item prior to his or her entitlement to supplemental medical

insurance (SMI) but receives the item after the effective date of SMI enrollment, the expense is considered incurred after entitlement began. However, if an item **not** custom-made for the beneficiary was ordered but not furnished, no reimbursement can be made. (See §20.3 for rules concerning custom-made items ordered but not furnished and the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for additional rules concerning the date of incurred expenses for durable medical equipment.)

20.1 - Physician Expense for Surgery, Childbirth, and Treatment for Infertility

(Rev. 1, 10-01-03)
B3-2005.l

A. Surgery and Childbirth

Skilled medical management is covered throughout the events of pregnancy, beginning with diagnosis, continuing through delivery and ending after the necessary postnatal care. Similarly, in the event of termination of pregnancy, regardless of whether terminated spontaneously or for therapeutic reasons (i.e., where the life of the mother would be endangered if the fetus were brought to term), the need for skilled medical management and/or medical services is equally important as in those cases carried to full term. After the infant is delivered and is a separate individual, items and services furnished to the infant are not covered on the basis of the mother's eligibility.

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Most surgeons and obstetricians bill patients an all-inclusive package charge intended to cover all services associated with the surgical procedure or delivery of the child. All expenses for surgical and obstetrical care, including preoperative/prenatal examinations and tests and post-operative/postnatal services, are considered incurred on the date of surgery or delivery, as appropriate. This policy applies whether the physician bills on a package charge basis, or itemizes the bill separately for these items.

Occasionally, a physician's bill may include charges for additional services not directly related to the surgical procedure or the delivery. Such charges are considered incurred on the date the additional services are furnished.

The above policy applies only where the charges are imposed by one physician or by a clinic on behalf of a group of physicians. Where more than one physician imposes charges for surgical or obstetrical services, all preoperative/prenatal and post-operative/postnatal services performed by the physician who performed the surgery or delivery are considered incurred on the date of the surgery or delivery. Expenses for services rendered by other physicians are considered incurred on the date they were performed.

B. Treatment for Infertility

Reasonable and necessary services associated with treatment for infertility are covered under Medicare. Infertility is a condition sufficiently at variance with the usual state of health to make it appropriate for a person who normally is expected to be fertile to seek medical consultation and treatment.

20.2 - Physician Expense for Allergy Treatment

(Rev. 1, 10-01-03)
B3-2005.2, B3-4145

Allergists commonly bill separately for the initial diagnostic workup and for the treatment (See §60.2). Where it is necessary to provide treatment over an extended period, the allergist may submit a single bill for all of the treatments, or may bill periodically. In either case the Form CMS-1500 claim shows the Healthcare Common Procedure Coding System (HCPCS) codes and from and through dates of service, or the Form CMS-1450 outpatient claim shows the HCPCS code and date of service (except for critical access hospital (CAH) claims).

20.3 - Artificial Limbs, Braces, and Other Custom Made Items Ordered But Not Furnished

(Rev. 1, 10-01-03)
B3-2005.3

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A. Date of Incurred Expense

If a custom-made item was ordered but not furnished to a beneficiary because the individual died or because the order was canceled by the beneficiary or because the beneficiary's condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made based on the supplier's expenses. (See subsection B for determination of the allowed amount.) In such cases, the expense is considered incurred on the date the beneficiary died or the date the supplier learned of the cancellation or that the item was no longer reasonable and necessary or appropriate for the beneficiary's condition. If the beneficiary died or the beneficiary's condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made on either an assigned or unassigned claim. If the beneficiary, for any other reason, canceled the order, payment can be made to the supplier only.

B. Determination of Allowed Amount

The allowed amount is based on the services furnished and materials used, up to the date the supplier learned of the beneficiary's death or of the cancellation of the order or that the item was no longer reasonable and necessary or appropriate. The Durable Medical Equipment Regional Carrier (DMERC), carrier or intermediary, as appropriate, determines the services performed and the allowable amount appropriate in the particular situation. It takes into account any salvage value of the device to the supplier.

Where a supplier breaches an agreement to make a prosthesis, brace, or other custom-made device for a Medicare beneficiary, e.g., an unexcused failure to provide the article within the time specified in the contract, payment may not be made for any work or material expended on the item. Whether a particular supplier has lived up to its agreement, of course, depends on the facts in the individual case.

30 - Physician Services

(Rev. 147, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11)

A. General

Physician services are the professional services performed by a physician or physicians for a patient including diagnosis, therapy, surgery, consultation, and care plan oversight.

The physician must render the service for the service to be covered. (See Pub. 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, §70, for definition of physician.) A service may be considered to be a physician's service where the physician either examines the patient in person or is able to visualize some aspect of the patient's condition without the interposition of a third person's judgment. Direct visualization would be possible by means of x-rays, electrocardiogram and electroencephalogram tapes, tissue samples, etc.

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For example, the interpretation by a physician of an actual electrocardiogram or electroencephalogram reading that has been transmitted via telephone (i.e., electronically rather than by means of a verbal description) is a covered service.

Professional services of the physician are covered if provided within the United States, and may be performed in a home, office, institution, or at the scene of an accident. A patient's home, for this purpose, is anywhere the patient makes his or her residence, e.g., home for the aged, a nursing home, a relative's home.

B. Telephone Services

Services by means of a telephone call between a physician and a beneficiary, or between a physician and a member of a beneficiary's family, are covered under Medicare, but carriers may not make separate payment for these services under the program. The physician work resulting from telephone calls is considered to be an integral part of the prework and postwork of other physician services, and the fee schedule amount for the latter services already includes payment for the telephone calls. See §270 of this manual for coverage of telehealth services.

C. Consultations

As of January 1, 2010, CMS no longer recognizes consultation codes for Medicare payment, except for inpatient telehealth consultation HCPCS G-codes. Instead, physicians and qualified nonphysician practitioners are instructed to bill a new or

established patient office/outpatient visit CPT code or appropriate hospital or nursing facility care code. For further detail regarding reporting services that would otherwise be described by the CPT consultation codes (99241-99245 and 99251-99255), see Pub. 100-04, Medicare Claims Processing Manual, chapter 12, section 30.6. For detailed instructions regarding reporting telehealth consultation services and other telehealth services, see Pub. 100-04, chapter 12, section 190.3.

D. Patient-Initiated Second Opinions

Patient-initiated second opinions that relate to the medical need for surgery or for major nonsurgical diagnostic and therapeutic procedures (e.g., invasive diagnostic techniques such as cardiac catheterization and gastroscopy) are covered under Medicare. In the event that the recommendation of the first and second physician differs regarding the need for surgery (or other major procedure), a third opinion is also covered. Second and third opinions are covered even though the surgery or other procedure, if performed, is determined not covered. Payment may be made for the history and examination of the patient, and for other covered diagnostic services required to properly evaluate the patient's need for a procedure and to render a professional opinion. In some cases, the results of tests done by the first physician may be available to the second physician.

E. Concurrent Care

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Concurrent care exists where more than one physician renders services more extensive than consultative services during a period of time. The reasonable and necessary services of each physician rendering concurrent care could be covered where each is required to play an active role in the patient's treatment, for example, because of the existence of more than one medical condition requiring diverse specialized medical services.

In order to determine whether concurrent physicians' services are reasonable and necessary, the carrier must decide the following:

1. Whether the patient's condition warrants the services of more than one physician on an attending (rather than consultative) basis, and

2. Whether the individual services provided by each physician are reasonable and necessary.

In resolving the first question, the carrier should consider the specialties of the physicians as well as the patient's diagnosis, as concurrent care is usually (although not always) initiated because of the existence of more than one medical condition requiring diverse specialized medical or surgical services. The specialties of the physicians are an indication of the necessity for concurrent services, but the patient's condition and the inherent reasonableness and necessity of the services, as determined by the carrier's medical staff in accordance with locality norms, must also be considered. For example, although cardiology is a sub-specialty of internal medicine, the treatment of both diabetes

and of a serious heart condition might require the concurrent services of two physicians, each practicing in internal medicine but specializing in different sub-specialties.

While it would not be highly unusual for concurrent care performed by physicians in different specialties (e.g., a surgeon and an internist) or by physicians in different subspecialties of the same specialty (e.g., an allergist and a cardiologist) to be found medically necessary, the need for such care by physicians in the same specialty or subspecialty (e.g., two internists or two cardiologists) would occur infrequently since in most cases both physicians would possess the skills and knowledge necessary to treat the patient. However, circumstances could arise which would necessitate such care. For example, a patient may require the services of two physicians in the same specialty or sub-specialty when one physician has further limited his or her practice to some unusual aspect of that specialty, e.g., tropical medicine. Similarly, concurrent services provided by a family physician and an internist may or may not be found to be reasonable and necessary, depending on the circumstances of the specific case. If it is determined that the services of one of the physicians are not warranted by the patient's condition, payment may be made only for the other physician's (or physicians') services.

Once it is determined that the patient requires the active services of more than one physician, the individual services must be examined for medical necessity, just as where a single physician provides the care. For example, even if it is determined that the patient requires the concurrent services of both a cardiologist and a surgeon, payment may not be made for any services rendered by either physician which, for that condition, exceed normal frequency or duration unless there are special circumstances requiring the additional care.

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The carrier must also assure that the services of one physician do not duplicate those provided by another, e.g., where the family physician visits during the post-operative period primarily as a courtesy to the patient.

Hospital admission services performed by two physicians for the same beneficiary on the same day could represent reasonable and necessary services, provided, as stated above, that the patient's condition necessitates treatment by both physicians. The level of difficulty of the service provided may vary between the physicians, depending on the severity of the complaint each one is treating and that physician's prior contact with the patient. For example, the admission services performed by a physician who has been treating a patient over a period of time for a chronic condition would not be as involved as the services performed by a physician who has had no prior contact with the patient and who has been called in to diagnose and treat a major acute condition.

Carriers should have sufficient means for identifying concurrent care situations. A correct coverage determination can be made on a concurrent care case only where the claim is sufficiently documented for the carrier to determine the role each physician played in the patient's care (i.e., the condition or conditions for which the physician treated the patient). If, in any case, the role of each physician involved is not clear, the carrier should request clarification.

F. Completion of Claims Forms

Separate charges for the services of a physician in completing a Form CMS-1500, a statement in lieu of a Form CMS-1500, or an itemized bill are not covered. Payment for completion of the Form CMS-1500 claim form is considered included in the fee schedule amount.

G. Care Plan Oversight Services

Care plan oversight is supervision of patients under care of home health agencies or hospices that require complex and multidisciplinary care modalities involving regular physician development and/or revision of care plans, review of subsequent reports of patient status, review of laboratory and other studies, communication with other health professionals not employed in the same practice who are involved in the patient's care, integration of new information into the care plan, and/or adjustment of medical therapy.

Such services are covered for home health and hospice patients, but are not covered for patients of skilled nursing facilities (SNFs), nursing home facilities, or hospitals.

These services are covered only if all the following requirements are met:

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1. The beneficiary must require complex or multi-disciplinary care modalities requiring ongoing physician involvement in the patient's plan of care;

2. The care plan oversight (CPO) services should be furnished during the period in which the beneficiary was receiving Medicare covered HHA or hospice services;

3. The physician who bills CPO must be the same physician who signed the home health or hospice plan of care;

4. The physician furnished at least 30 minutes of care plan oversight within the calendar month for which payment is claimed. Time spent by a physician's nurse or the time spent consulting with one's nurse is not countable toward the 30-minute threshold. Low-intensity services included as part of other evaluation and management services are not included as part of the 30 minutes required for coverage;

5. The work included in hospital discharge day management (codes 99238-99239) and discharge from observation (code 99217) is not countable toward the 30 minutes per month required for work on the same day as discharge but only for those services separately documented as occurring after the patient is actually physically discharged from the hospital;

6. The physician provided a covered physician service that required a face-to-face encounter with the beneficiary within the 6 months immediately preceding the

first care plan oversight service. Only evaluation and management services are acceptable prerequisite face-to-face encounters for CPO. EKG, lab, and surgical services are not sufficient face-to-face services for CPO;

7. The care plan oversight billed by the physician was not routine post-operative care provided in the global surgical period of a surgical procedure billed by the physician;

8. If the beneficiary is receiving home health agency services, the physician did not have a significant financial or contractual interest in the home health agency. A physician who is an employee of a hospice, including a volunteer medical director, should not bill CPO services. Payment for the services of a physician employed by the hospice is included in the payment to the hospice;

9. The physician who bills the care plan oversight services is the physician who furnished them;

10. Services provided incident to a physician's service do not qualify as CPO and do not count toward the 30-minute requirement;

11. The physician is not billing for the Medicare end stage renal disease (ESRD) capitation payment for the same beneficiary during the same month; and

12. The physician billing for CPO must document in the patient's record the services furnished and the date and length of time associated with those services.

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30.1 - Provider-Based Physician Services

(Rev. 1, 10-01-03)
A3-3145, B3-2020.6, B3-8000-8099 (only instructions still applicable are included)

Providers may retain physicians on a full-time or part-time basis in, for example, the fields of pathology, psychiatry, anesthesiology, and radiology, and in many instances (especially in teaching hospitals) in other fields of medical specialization as well. Any one of these physicians may be engaged in a variety of activities including teaching, research, administration, supervision of professional or technical personnel, service on hospital committees, and other hospital-wide activities, as well as direct medical services to individual patients. The provider's arrangement may be with a single physician or with a group of physicians who assume joint responsibility for discharging agreed-upon duties.

It is necessary to distinguish between the medical and surgical services rendered by a physician to an individual patient, which are paid under Part B, and provider services (including a physician's services for the provider) which are paid under Part A. This is necessary because the payments are made from different trust funds, both intermediaries and carriers are involved in handling the claims, and the method of determining the payments for Part A benefits differs from the Part B payment calculation.

Provider-based physicians may include those on a salary, or a percentage arrangement, lessors of departments, etc. (whether or not they bill patients directly). The services to the patient are known as the professional component. The services to the provider are known as the provider component.

A. The Professional Component

The professional component of a provider-based physician's services pertains to that part of the physician's activities that is directly related to the medical care of the individual patient. It represents remuneration for the identifiable medical services by the physician that contribute to the diagnosis of the patient's condition or to his treatment. These services are covered under Part B. Claims for professional services are processed by the carrier and are paid, where applicable, under the fee schedule.

B. The Provider Component

The portion of the physician's activities representing services which are not directly related to an identifiable part of the medical care of the individual patient is the provider component. Payment for provider component services can be made only to a provider, and is included in the provider's prospective payment system (PPS) rate. Provider services include teaching, research conducted in conjunction with and as part of patient care (to the extent that such costs are not met by special research funds), administration, general supervision of professional or technical personnel, laboratory quality control activities, committee work, performance of autopsies, and attending conferences as part of the physician's provider service activities. Such services are covered under Part A where they relate to inpatient services.

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30.2 - Teaching Physician Services

(Rev. 1, 10-01-03)
B3-2020.7, B3-8201, and B3-15016

Part B covers services that attending physicians (other than interns and residents) render in the teaching setting to individual patients. These include such services as reviewing the patient's history and physical exams, personally examining the patient within a reasonable time after admission, confirming or revising diagnoses, determining the course of treatment to be followed, assuring that any supervision needed by interns or residents is furnished, and making frequent review of the patient's progress. The medical record must contain signed or countersigned notes by the physician which show that the physician personally reviewed the patient's diagnoses, visited the patient at more critical times of the illness, and discharged the patient. For other services, such as surgical procedures, notes in the record by interns, residents, or nurses, which indicate that the physician was physically present when the service was rendered, are sufficient.

Note that, in order to pay a teaching physician under Part B, the teaching physician must at least be present during the key portion of a service rendered by a resident or intern.

When a resident does a visit without teaching physician presence, the teaching physician must repeat the key portions of the visit and have his own documentation in order to get paid.

30.3 - Interns and Residents

(Rev. 1, 10-01-03)
B3-2020.8, A3-3115

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 payment. As a general rule, the intermediary pays for services of interns and residents as provider services.

A. 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, provider services includes medical and surgical services furnished in a setting that is not part of the provider, where the hospital has agreed to incur all or substantially all of the costs of training in the nonprovider facility.

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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 payable under Part B by the carrier.

B. 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 physician services where the requirements in the first two bullets 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 where all three of the following criteria are met:

- The services are identifiable physician services, the nature of which requires performance by a physician in person and which contribute to the diagnosis or treatment of the patient's condition;

- The intern or resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and

- 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.

30.4 - Optometrist's Services

(Rev. 1, 10-01-03)
B3-2020.25

Effective April 1, 1987, a doctor of optometry is considered a physician with respect to all services the optometrist is authorized to perform under State law or regulation. To be covered under Medicare, the services must be medically reasonable and necessary for the diagnosis or treatment of illness or injury, and must meet all applicable coverage requirements. See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," for exclusions from coverage that apply to vision care services, and the Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioner Billing," for information dealing with payment for items and services furnished by optometrists.

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A. FDA Monitored Studies of Intraocular Lenses

Special coverage rules apply to situations in which an ophthalmologist is involved in a Food and Drug Administration (FDA) monitored study of the safety and efficacy of an investigational Intraocular Lens (IOL). The investigation process for IOLs is unique in that there is a core period and an adjunct period. The core study is a traditional, well-controlled clinical investigation with full record keeping and reporting requirements. The adjunct study is essentially an extended distribution phase for lenses in which only limited safety data are compiled. Depending on the lens being evaluated, the adjunct study may be an extension of the core study or may be the only type of investigation to which the lens may be subject.

All eye care services related to the investigation of the IOL must be provided by the investigator (i.e., the implanting ophthalmologist) or another practitioner (including a doctor of optometry) who provides services at the direction or under the supervision of the investigator and who has an agreement with the investigator that information on the patient is given to the investigator so that he or she may report on the patient to the IOL manufacturer.

Eye care services furnished by anyone other than the investigator (or a practitioner who assists the investigator, as described in the preceding paragraph) are not covered during the period the IOL is being investigated, unless the services are not related to the investigation.

B. Concurrent Care

Where more than one practitioner furnishes concurrent care, services furnished to a beneficiary by both an ophthalmologist and another physician (including an optometrist) may be recognized for payment if it is determined that each practitioner's services were reasonable and necessary. (See §30.E.)

30.5 - Chiropractor's Services

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)
B3-2020.26

A chiropractor must be licensed or legally authorized to furnish chiropractic services by the State or jurisdiction in which the services are furnished. In addition, a licensed chiropractor must meet the following uniform minimum standards to be considered a physician for Medicare coverage. Coverage extends only to treatment by means of manual manipulation of the spine to correct a subluxation provided such treatment is legal in the State where performed. All other services furnished or ordered by chiropractors are not covered.

If a chiropractor orders, takes, or interprets an x-ray or other diagnostic procedure to demonstrate a subluxation of the spine, the x-ray can be used for documentation. However, there is no coverage or payment for these services or for any other diagnostic or therapeutic service ordered or furnished by the chiropractor. For detailed information on using x-rays to determine subluxation, see §240.1.2.

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In addition, in performing manual manipulation of the spine, some chiropractors use manual devices that are hand-held with the thrust of the force of the device being controlled manually. While such manual manipulation may be covered, there is no separate payment permitted for use of this device.

A. Uniform Minimum Standards

Prior to July 1, 1974

Chiropractors licensed or authorized to practice prior to July 1, 1974, and those individuals who commenced their studies in a chiropractic college before that date must meet all of the following three minimum standards to render payable services under the program:

- Preliminary education equal to the requirements for graduation from an accredited high school or other secondary school;

- Graduation from a college of chiropractic approved by the State's chiropractic examiners that included the completion of a course of study covering a period of not less than 3 school years of 6 months each year in actual continuous

attendance covering adequate course of study in the subjects of anatomy, physiology, symptomatology and diagnosis, hygiene and sanitation, chemistry, histology, pathology, and principles and practice of chiropractic, including clinical instruction in vertebral palpation, nerve tracing, and adjusting; and

- Passage of an examination prescribed by the State's chiropractic examiners covering the subjects listed above.

After June 30, 1974

Individuals commencing their studies in a chiropractic college after June 30, 1974, must meet all of the above three standards and all of the following additional requirements:

- Satisfactory completion of 2 years of pre-chiropractic study at the college level;

- Satisfactory completion of a 4-year course of 8 months each year (instead of a 3-year course of 6 months each year) at a college or school of chiropractic that includes not less than 4,000 hours in the scientific and chiropractic courses specified in the second bullet under "**Prior to July 1, 1974**" above, plus courses in the use and effect of x-ray and chiropractic analysis; and

- The practitioner must be over 21 years of age.

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B. Maintenance Therapy

Under the Medicare program, chiropractic maintenance therapy is not considered to be medically reasonable or necessary, and is therefore not payable. Maintenance therapy is defined as a treatment plan that seeks to prevent disease, promote health, and prolong and enhance the quality of life; or therapy that is performed to maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. For information on how to indicate on a claim a treatment is or is not maintenance, see §240.1.3.

30.6 - Indian Health Service (IHS) Physician and Nonphysician Services

(Rev. 86, Issued: 04-18-08, Effective: 09-11-06, Implementation: 05-19-08)

This information can also be found in the Medicare Claims Processing Manual, Publication 100-04, chapter 19.

Section 1880 of Title XVIII of the Social Security Act (the Act) provides an exception for Indian Health Service to the general prohibition of payment to Federal Agencies.

The following facilities, which were unable to bill for practitioner services prior to BIPA, may now be paid:

- Outpatient departments of IHS operated hospitals that meet the definition of provider-based in 42 CFR 413.65; and

- Outpatient clinics (freestanding) operated by the IHS.

The following facilities, which were limited by §1880 of the Act, may be paid for services under BIPA or may be paid under another authority under which it qualifies.

- Outpatient departments of tribally operated hospitals that are operated by a tribe or tribal organization; and

- Other outpatient facilities that are tribally operated regardless of ownership.

See the Medicare Claims Processing Manual chapter 19 for a description of billing procedures, physician and non-physician services and other Part B services.

30.6.1 - Payment for Medicare Part B Services Furnished by Certain IHS Hospitals and Clinics

(Rev. 86, Issued: 04-18-08, Effective: 09-11-06, Implementation: 05-19-08)

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Section 1880 of the Act, as amended by §630 of the Medicare Modernization Act of 2003 (MMA), expands the scope of items and services for which payment may be made to IHS facilities, providers and suppliers to include all Part B covered items and services for which payment may be made under Part B, subject to certain limitations as specified in §1880(e)(1)(A) of the Act, for a 5-year period beginning January 1, 2005.

Specifically, for the 5-year period beginning January 1, 2005, IHS facilities, providers and suppliers may bill Medicare for the following Part B services:

- Durable medical equipment
- Prosthetics and orthotics
- Prosthetics devices
- Therapeutic shoes
- Surgical dressings and splint casts
- Drugs (Part B and DMERC)
- Clinical laboratory services, and
- Ambulance services
- Screening and preventive services not already covered

See Pub. 100.04, chapter 19, Medicare Claims Processing Manual, for more information on these benefits and the effective date for each of these benefits.

40 - Effect of Beneficiary Agreements Not to Use Medicare Coverage

(Rev. 1, 10-01-03)
B3-3044, PM-B-97-17

Normally physicians and practitioners are required to submit claims on behalf of beneficiaries for all items and services they provide for which Medicare payment may be made under Part B. Also, they are not allowed to charge beneficiaries in excess of the limits on charges that apply to the item or service being furnished.

However, a physician or practitioner (as defined in §40.4) may opt out of Medicare. A physician or practitioner who opts out is not required to submit claims on behalf of beneficiaries and also is excluded from limits on charges for Medicare covered services.

Only physicians and practitioners that are listed in §40.4 may opt out.

- The **only** situation in which non-opt-out physicians or practitioners, or other suppliers, are not required to submit claims to Medicare for covered services is where a beneficiary or the beneficiary's legal representative refuses, of his/her own free will, to authorize the submission of a bill to Medicare. However, the limits on what the physician, practitioner, or other supplier may collect from the beneficiary continue to apply to charges for the covered service, notwithstanding the absence of a claim to Medicare.

- If an item or service is one that Medicare may cover in some circumstances but not in others, a non-opt-out physician/practitioner, or other supplier, must still submit a claim to Medicare. However, the physician, practitioner or other supplier may choose to provide the beneficiary, prior to the rendering of the item or service, an Advance Beneficiary Notice (ABN) as described in the Medicare Claims Processing Manual Chapter 30. (Also see §40.24 for a description of the difference between an ABN and a private contract.) An ABN notifies the beneficiary that Medicare is likely to deny the claim and that if Medicare does deny the claim, the beneficiary will be liable for the full cost of the services. Where a valid ABN is given, subsequent denial of the claim relieves the non-opt-out physician/practitioner, or other supplier, of the limitations on charges that would apply if the services were covered.

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Opt-out physicians and practitioners must not use ABNs, because they use private contracts for any item or service that is, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)).

Where a physician/practitioner, or other supplier, fails to submit a claim to Medicare on behalf of a beneficiary for a covered Part B service within one year of providing the service, or knowingly and willfully charges a beneficiary more than the applicable charge limits on a repeated basis, he/she/it may be subject to civil monetary penalties under §§1848(g)(1) and/or 1848(g)(3) of the Act. Congress enacted these requirements for the protection of all Part B beneficiaries. Application of these requirements cannot be negotiated between a physician/practitioner or other supplier and the beneficiary except where a physician/practitioner is eligible to opt out of Medicare under §40.4 and the remaining requirements of §§40.1 - 40.38 are met. Agreements with Medicare

beneficiaries that are not authorized as described in these manual sections and that purport to waive the claims filing or charge limitations requirements, or other Medicare requirements, have no legal force and effect. For example, an agreement between a physician/practitioner, or other supplier and a beneficiary to exclude services from Medicare coverage, or to excuse mandatory assignment requirements applicable to certain practitioners, is ineffective.

The contractor will refer such cases to the OIG.

This subsection does not apply to noncovered charges.

40.1 - Private Contracts Between Beneficiaries and Physicians/Practitioners

(Rev. 1, 10-01-03)
B3-3044.1

Section 1802 of the Act, as amended by §4507 of the BBA of 1997, permits a physician/practitioner to opt out of Medicare and enter into private contracts with Medicare beneficiaries if specific requirements of this instruction are met.

40.2 - General Rules of Private Contracts

(Rev. 1, 10-01-03)
B3-3044.2

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The following rules apply to physicians/practitioners who opt out of Medicare:

- A physician/practitioner may enter into one or more private contracts with Medicare beneficiaries for the purpose of furnishing items or services that would otherwise be covered by Medicare (provided the conditions in §40.1 are met).

- A physician/practitioner who enters into at least one private contract with a Medicare beneficiary (under the conditions of §40.1) and who submits one or more affidavits in accordance with §40.9, opts out of Medicare for a 2-year period unless the opt-out is terminated early according to §40.35 or unless the physician/practitioner fails to maintain opt-out. (See §40.11.) The physician's or practitioner's opt out may be renewed for subsequent 2-year periods.

- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt out described in the second paragraph of this section are null and void if the physician/practitioner fails to properly opt out in accordance with the conditions of these instructions.

- Both the private contracts described in the first paragraph of this section and the physician's or practitioner's opt out described in the second paragraph of this section are null and void for the remainder of the opt-out period if the

physician/practitioner fails to remain in compliance with the conditions of these instructions during the opt-out period.

- Services furnished under private contracts meeting the requirements of these instructions are not covered services under Medicare, and no Medicare payment will be made for such services either directly or indirectly.

40.3 - Effective Date of the Opt-Out Provision

(Rev. 1, 10-01-03)
B3-3044.3

A physician/practitioner may enter into a private contract with a beneficiary for services furnished no earlier than January 1, 1998.

40.4 - Definition of Physician/Practitioner

(Rev. 62, Issued: 12-22-06, Effective: 11-13-06, Implementation: 04-02-07)

For purposes of this provision, the term "physician" is limited to doctors of medicine; doctors of osteopathy; doctors of dental surgery or of dental medicine; doctors of podiatric medicine; and doctors of optometry who are legally authorized to practice dentistry, podiatry, optometry, medicine, or surgery by the State in which such function or action is performed; no other physicians may opt out. Also, for purposes of this provision, the term "practitioner" means any of the following to the extent that they are legally authorized to practice by the State and otherwise meet Medicare requirements:

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- Physician assistant;
- Nurse practitioner;
- Clinical nurse specialist;
- Certified registered nurse anesthetist;
- Certified nurse midwife;
- Clinical psychologist;
- Clinical social worker;
- Registered dietitian; or
- Nutrition Professional

The opt out law does not define "physician" to include chiropractors; therefore, they may not opt out of Medicare and provide services under private contract. Physical therapists in independent practice and occupational therapists in independent practice cannot opt out because they are not within the opt out law's definition of either a "physician" or "practitioner".

40.5 - When a Physician or Practitioner Opts Out of Medicare

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

When a physician/practitioner opts out of Medicare, Medicare covers no services provided by that individual and no Medicare payment can be made to that physician or practitioner directly or on a capitated basis. Additionally, no Medicare payment may be made to a beneficiary for items or services provided directly by a physician or practitioner who has opted out of the program.

EXCEPTION: In an emergency or urgent care situation, a physician/practitioner who opts out may treat a Medicare beneficiary with whom he/she does not have a private contract and bill for such treatment. In such a situation, the physician/practitioner may not charge the beneficiary more than what a nonparticipating physician/practitioner would be permitted to charge and must submit a claim to Medicare on the beneficiary's behalf. Payment will be made for Medicare covered items or services furnished in emergency or urgent situations when the beneficiary has not signed a private contract with that physician/practitioner. (See §40.28.)

Under the statute, the physician/practitioner cannot choose to opt out of Medicare for some Medicare beneficiaries but not others; or for some services but not others. The physician/practitioner who chooses to opt out of Medicare may provide covered care to Medicare beneficiaries only through private agreements.

Medicare will make payment for covered, medically necessary services that are ordered by a physician/practitioner who has opted out of Medicare if the ordering physician/practitioner has acquired a National Provider Identifier (NPI) and provided that the services are not furnished by another physician/practitioner who has also opted out. For example, if an opt-out physician/practitioner admits a beneficiary to a hospital, Medicare will reimburse the hospital for medically necessary care.

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40.6 - When Payment May be Made to a Beneficiary for Service of an Opt-Out Physician/Practitioner

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

Payment may be made to a beneficiary for services of an opt out physician/practitioner in two cases:

- The services are emergency or urgent care services furnished by an opt-out physician/practitioner to a beneficiary with whom he/she has not previously entered into a private contract. (See §40.28 for further discussion of emergency and urgent care services by opt-out physicians and practitioners.); or

- The opt-out physician/practitioner failed to privately contract with the beneficiary for services that he/she provided that were not emergency or urgent care services. The CMS expects this case to come to the carrier's attention only in the course of a request for a redetermination of a denied claim or as a result of a complaint from a beneficiary or the beneficiary's legal representative. If the carrier receives such a complaint, it must consider it to be a request for a redetermination of the denial of payment for services of the opt-out physician/practitioner. It must follow the procedures outlined in §40.11 for

cases in which the physician/ practitioner fails to maintain opt-out. If the physician/practitioner does not respond to the carrier's request for a copy of the private contract within 45 days, the carrier must make payment to the beneficiary based upon the payment for a nonparticipating physician/practitioner for that service. It must notify the beneficiary that the physician/practitioner who has opted out must privately contract with the beneficiary or the beneficiary's legal representative for services the physician/practitioner furnished and that no further payment will be made to the beneficiary for services furnished by the opt-out physician/practitioner after 15 days from the postmark of the notice.

40.7 - Definition of a Private Contract

(Rev. 1, 10-01-03)
B3-3044.7

A "private contract" is a contract between a Medicare beneficiary and a physician or other practitioner who has opted out of Medicare for two years for **all** covered items and services the physician/practitioner furnishes to Medicare beneficiaries. In a private contract, the Medicare beneficiary agrees to give up Medicare payment for services furnished by the physician/practitioner and to pay the physician/practitioner without regard to any limits that would otherwise apply to what the physician/practitioner could charge. Pursuant to the statute, once a physician/practitioner files an affidavit notifying the Medicare carrier that the he/she has opted out of Medicare, the physician/practitioner is out of Medicare for two years from the date the affidavit is signed (unless the opt-out is terminated early according to §40.35, or unless the he/she fails to maintain opt-out (See §40.11)). After those two years are over, a physician/practitioner could elect to return to Medicare or to opt out again. A beneficiary who signs a private contract with a physician/practitioner is not precluded from receiving services from other physicians and practitioners who have not opted out of Medicare.

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Physicians or practitioners who provide services to Medicare beneficiaries enrolled in the new Medical Savings Account (MSA) demonstration created by the BBA of 1997 are not required to enter into a private contract with those beneficiaries and to opt out of Medicare under §1802 of the Act.

40.8 - Requirements of a Private Contract

(Rev. 1, 10-01-03)
B3-3044.8

A private contract under this section must:

- Be in writing and in print sufficiently large to ensure that the beneficiary is able to read the contract;
- Clearly state whether the physician/practitioner is excluded from Medicare under §§1128, 1156 or 1892 of the Act;

- State that the beneficiary or the beneficiary's legal representative accepts full responsibility for payment of the physician's or practitioner's charge for all services furnished by the physician/practitioner;

- State that the beneficiary or the beneficiary's legal representative understands that Medicare limits do not apply to what the physician/practitioner may charge for items or services furnished by the physician/practitioner;

- State that the beneficiary or the beneficiary's legal representative agrees not to submit a claim to Medicare or to ask the physician/practitioner to submit a claim to Medicare;

- State that the beneficiary or the beneficiary's legal representative understands that Medicare payment will not be made for any items or services furnished by the physician/practitioner that would have otherwise been covered by Medicare if there was no private contract and a proper Medicare claim had been submitted;

- State that the beneficiary or the beneficiary's legal representative enters into the contract with the knowledge that the beneficiary has the right to obtain Medicare-covered items and services from physicians and practitioners who have not opted out of Medicare, and that the beneficiary is not compelled to enter into private contracts that apply to other Medicare-covered services furnished by other physicians or practitioners who have not opted out;

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- State the expected or known effective date and expected or known expiration date of the opt-out period;

- State that the beneficiary or the beneficiary's legal representative understands that Medigap plans do not, and that other supplemental plans may elect not to, make payments for items and services not paid for by Medicare;

- Be signed by the beneficiary or the beneficiary's legal representative and by the physician/practitioner;

- Not be entered into by the beneficiary or by the beneficiary's legal representative during a time when the beneficiary requires emergency care services or urgent care services. (However, a physician/practitioner may furnish emergency or urgent care services to a Medicare beneficiary in accordance with §40.28;)

- Be provided (a photocopy is permissible) to the beneficiary or to the beneficiary's legal representative before items or services are furnished to the beneficiary under the terms of the contract;

- Be retained (original signatures of both parties required) by the physician/practitioner for the duration of the opt-out period;

- Be made available to CMS upon request; and

- Be entered into for each opt-out period.

In order for a private contract with a beneficiary to be effective, the physician/practitioner must file an affidavit with all Medicare carriers to which the physician/practitioner would submit claims, advising that the physician/practitioner has opted out of Medicare. The affidavit must be filed within 10 days of entering into the first private contract with a Medicare beneficiary. Once the physician/practitioner has opted out, such physician/practitioner must enter into a private contract with each Medicare beneficiary to whom the physician/practitioner furnishes covered services (even where Medicare payment would be on a capitated basis or where Medicare would pay an organization for the physician's or practitioner's services to the Medicare beneficiary), with the exception of a Medicare beneficiary needing emergency or urgent care.

If a physician/practitioner has opted out of Medicare, the physician/practitioner must use a private contract for items and services that are, or may be, covered by Medicare (except for emergency or urgent care services (see §40.28)). An opt-out physician/practitioner is not required to use a private contract for an item or service that is definitely excluded from coverage by Medicare.
A non-opt-out physician/practitioner, or other supplier, is required to submit a claim for any item or service that is, or may be, covered by Medicare. Where an item or service may be covered in some circumstances, but not in others, the physician/practitioner, or other supplier, may provide an Advance Beneficiary Notice to the beneficiary, which informs the beneficiary that Medicare may not pay for the item or service, and that if Medicare does not do so, the beneficiary is liable for the full charge. (See §§40, 40.24)

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40.9 - Requirements of the Opt-Out Affidavit
(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

Under 1802(b)(3)(B) of the Act, a valid affidavit must:

- Be in writing and be signed by the physician/practitioner;

- Contain the physician's or practitioner's full name, address, telephone number, national provider identifier (NPI) or billing number (if one has been assigned), or, if an NPI has not been assigned, the physician's or practitioner's tax identification number (TIN);

- State that, except for emergency or urgent care services (as specified in §40.28), during the opt-out period the physician/practitioner will provide services to Medicare beneficiaries only through private contracts that meet the criteria of §40.8 for services that, but for their provision under a private contract, would have been Medicare-covered services;

- State that the physician/practitioner will not submit a claim to Medicare for any service furnished to a Medicare beneficiary during the opt-out period, nor will the physician/practitioner permit any entity acting on the physician's/practitioner's behalf to submit a claim to Medicare for services furnished to a Medicare beneficiary, except as specified in §40.28;

- State that, during the opt-out period, the physician/practitioner understands that the physician/practitioner may receive no direct or indirect Medicare payment for services that the physician/practitioner furnishes to Medicare beneficiaries with whom the physician/practitioner has privately contracted, whether as an individual, an employee of an organization, a partner in a partnership, under a reassignment of benefits, or as payment for a service furnished to a Medicare beneficiary under a Medicare Advantage plan;

- State that a physician/practitioner who opts out of Medicare acknowledges that, during the opt-out period, the physician's/practitioner's services are not covered under Medicare and that no Medicare payment may be made to any entity for the physician's/practitioner's services, directly or on a capitated basis;

- State on acknowledgment by the physician/practitioner to the effect that, during the opt-out period, the physician/practitioner agrees to be bound by the terms of both the affidavit and the private contracts that the physician/practitioner has entered into;

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- Acknowledge that the physician/practitioner recognizes that the terms of the affidavit apply to all Medicare-covered items and services furnished to Medicare beneficiaries by the physician/practitioner during the opt-out period (except for emergency or urgent care services furnished to the beneficiaries with whom the physician/practitioner has not previously privately contracted) without regard to any payment arrangements the physician/practitioner may make;

- With respect to a physician/practitioner who has signed a Part B participation agreement, acknowledge that such agreement terminates on the effective date of the affidavit;

- Acknowledge that the physician/practitioner understands that a beneficiary who has not entered into a private contract and who requires emergency or urgent care services may not be asked to enter into a private contract with respect to receiving such services and that the rules of §40.28 apply if the physician/practitioner furnishes such services;

- Identify the physician/practitioner sufficiently so that the carrier can ensure that no payment is made to the physician/practitioner during the opt-out period; and

- Be filed with all carriers who have jurisdiction over claims the physician/practitioner would otherwise file with Medicare and be filed no later than 10 days after the first private contract to which the affidavit applies is entered into.

40.10 - Failure to Properly Opt Out

(Rev. 1, 10-01-03)
B3-3044.10

A. A physician/practitioner fails to properly opt out for any of the following reasons:

- Any private contract between the physician/practitioner and a Medicare beneficiary that was entered into before the affidavit described in §40.9 was filed does not meet the specifications of §40.8; or

- The physician/practitioner fails to submit the affidavit(s) in accordance with §40.9.

B. If a physician/practitioner fails to properly opt out in accordance with the above paragraphs of this section, the following will result:

- The physician's or practitioner's attempt to opt out of Medicare is nullified, and all of the private contracts between the physician/practitioner and Medicare beneficiaries for the two-year period covered by the attempted opt out are deemed null and void;

- The physician/practitioner must submit claims to Medicare for all Medicare-covered items and services furnished to Medicare beneficiaries, including the items and services furnished under the nullified contracts. A nonparticipating physician/practitioner is subject to the limiting charge provision. For items or services paid under the physician fee schedule, the limiting charge is 115 percent of the approved amount for nonparticipating physicians or practitioners. A participating physician/practitioner is subject to the limitations on charges of the participation agreement the physician/practitioner signed;

- The physician/practitioner may not reassign any claim except as provided in the Medicare Clams Processing Manual, Chapter 1, "General Billing Requirements," §§30.2.12 and 30.2.13;

- The physician/practitioner may neither bill nor collect an amount from the beneficiary except for applicable deductible and coinsurance amounts; and

- The physician/practitioner may make another attempt to properly opt out at any time.

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40.11 - Failure to Maintain Opt-Out

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

A. Failure to maintain opt-out

A physician/practitioner fails to maintain opt-out under this section if during the opt-out period one of the following occurs:

- The physician/practitioner has filed an affidavit in accordance with §40.9 and has signed private contracts in accordance with §40.8 but, the physician/practitioner knowingly and willfully submits a claim for Medicare payment (except as provided in §40.28) or the physician/practitioner receives Medicare payment directly or indirectly for Medicare-covered services furnished to a Medicare beneficiary (except as provided in §40.28); or

- The physician/practitioner fails to enter into private contracts with Medicare beneficiaries for the purpose of furnishing items and services that would otherwise be covered by Medicare, or enters into private contracts that fail to meet the specifications of §40.8; or

- The physician/practitioner fails to comply with the provisions of §40.28 regarding billing for emergency care services or urgent care services; or

- The physician/practitioner fails to retain a copy of each private contract that the physician/practitioner has entered into for the duration of the opt-out period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

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B. Violation discovered by the carrier during the 2-year opt out period.

If a physician/practitioner fails to maintain opt-out in accordance with the provisions outlined in paragraph A. of this section, and fails to demonstrate within 45 days of a notice from the carrier that the physician/practitioner has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to the beneficiaries with whom the physician/practitioner did not sign a private contract), the following will result effective 46 days after the date of the notice, **but only for the remainder of the opt-out period:**

1. All of the private contracts between the physician/practitioner and Medicare beneficiaries are deemed null and void.

2. The physician's or practitioner's opt-out of Medicare is nullified.

3. The physician or practitioner must submit claims to Medicare for all Medicare covered items and services furnished to Medicare beneficiaries.

4. The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as stated above.

5. The physician or practitioner is subject to the limiting charge provisions as stated in §40.10.

6. The practitioner may not reassign any claim except as provided in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §30.2.13.

7. The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.

8. The physician or practitioner may not attempt to once more meet the criteria for properly opting out until the 2-year opt-out period expires.

C. Violation <u>not</u> discovered by the carrier during the 2-year opt out period.

- In situations where a violation of paragraph (A) of this section is not discovered by the carrier during the 2-year opt-out period when the violation actually occurred, the requirements of paragraphs (B)(1) through (B)(8) of this section are applicable from the date that the first violation of paragraph (A) of this section occurred until the end of the opt-out period during which the violation occurred (unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the carrier that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (A) of this section. Good faith efforts include, but are not necessarily limited to, refunding any amounts collected in excess of the charge limits from beneficiaries with whom he or she did not sign a private contract).

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40.12 - Actions to Take in Cases of Failure to Maintain Opt-Out

(Rev. 1, 10-01-03)
B3-3044.12

If the carrier becomes aware that the physician/practitioner has failed to maintain opt-out as indicated in <u>§40.11</u>, it must send the physician/practitioner a letter advising the physician/practitioner that it has received a claim and believes that the physician/ practitioner may have inadvertently failed to maintain opt-out. It must describe the situation in §40.11 that it believes exists and its basis for its belief. It must ask the physician or practitioner to provide it with an explanation within 45 days of what happened and how the physician or practitioner will resolve it. (See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §70.6, and the Medicare Program Integrity Manual for action when responses are not received within 45 days).

If the carrier received a claim from the opt-out physician/practitioner, it must ask the physician/practitioner if the received claim was: (a) an emergency or urgent situation, with missing documentation, **or** (b) filed in error. When the reason for the letter is that the physician/practitioner filed a claim that the physician/practitioner did not identify as an emergency or urgent care service, the carrier must request that the physician/practitioner submit the following information with the physician's/practitioner's response:

- Emergency/urgent care documentation if the claim was for a service furnished in an emergency or urgent situation but included no documentation to that effect; and/or

- If the claim was filed in error, the carrier must ask the physician/practitioner to explain whether the filing was an isolated incident or a systematic problem affecting a number of claims.

In the case of any potential failure to maintain opt-out (including but not limited to improper submission of a claim), the carrier must explain in its request to the physician or practitioner that it would like to resolve this matter as soon as possible. It must instruct the physician/practitioner to provide the information it requested within 45 days of the date of its development letter. It must provide the physician or practitioner with the name and telephone number of a contact person in case they have any questions.

If the violation was due to a systems problem, the carrier must ask the physician or practitioner to include with his or her response an explanation of the actions being taken to correct the problem and when the physician or practitioner expects the system error to be fixed. If the violation persists beyond the time period indicated in the physician's or practitioner's response, the carrier must contact the physician or practitioner again to ascertain why the problem still exists and when the physician or practitioner expects to have it corrected. It must repeat this process until the system problem is corrected.

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Also, in the carrier's development request, it must advise the physician or practitioner that if no response is received by the due date, the carrier will assume that there has been no correction of the failure to maintain opt-out and that this could result in a determination that the physician/practitioner is once again subject to Medicare rules.

In the case of wrongly filed claims, the carrier must hold the claim and any others it receives from the physician or practitioner in suspense until it hears from the physician or practitioner or the response date lapses. In this case, if the physician or practitioner responds that the claim was filed in error, the carrier must continue processing the claim, deny the claim, and send the physician or practitioner the appropriate Remittance Advice and send the beneficiary a Medicare Summary Notice (MSN) with the appropriate language explaining that the claim was submitted erroneously and the beneficiary is responsible for the physician's or practitioner's charge. In other words, the limiting charge provision does not apply and the beneficiary is responsible for all charges. This process will apply to all claims until the physician or practitioner is able to get the problem fixed.

If the carrier does not receive a response from the physician or practitioner by the development letter due date or if it is determined that the opt-out physician or practitioner knowingly and willfully failed to maintain opt-out, it must notify the physician or practitioner that the effects of failure to maintain opt-out specified in <u>§40.11</u> apply. **It must formally notify the physician/practitioner of this determination and of the**

rules that again apply (e.g., mandatory submission of claims, limiting charge, etc.). It must specifically include in this letter each of the effects of failing to opt out that are identified in §40.11.

The act of claims submission by the beneficiary for an item or service provided by a physician or practitioner who has opted out is **not** a violation by the physician or practitioner and does not nullify the contract with the beneficiary. However, if there are what the carrier considers to be a substantial number of claims submissions by beneficiaries for items or services by an opt-out physician or practitioner, it must investigate to ensure that contracts between the physician or practitioner and the beneficiaries exist and that the terms of the contracts meet the Medicare statutory requirements outlined in this instruction. If noncompliance with the opt-out affidavit is determined, it must develop claims submission or limiting charge violation cases, as appropriate, based on its findings.

In cases in which the beneficiary files an appeal of the denial of a beneficiary-filed claim for services from an opt-out physician or practitioner, and alleges that there was no private contract, the carrier must ask the physician/practitioner to provide it with a copy of the private contract, but only if the beneficiary authorizes the carrier to do so. Where the physician or practitioner does not provide a copy of a private contract that was signed by the beneficiary before the service was furnished, the carrier must make payment to the beneficiary and proceed as described above.

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40.13 - Physician/Practitioner Who Has Never Enrolled in Medicare

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

For a physician/practitioner who has never enrolled in the Medicare program and wishes to opt out of Medicare, the physician/practitioner must provide the carrier with a National Provider Identifier (NPI). The carrier must annotate its in-house provider file that the physician/practitioner has opted out of the program. The carrier can get the full name, address, license number, and tax identification number from the physician's/practitioner's opt out affidavit. All other data requirements should be developed from other data sources (e.g., the American Medical Association, State Licensing Board, etc.). The physician/practitioner must not receive payment during the opt-out period (except in the case of emergency or urgent care services). If the carrier needs additional data elements and cannot obtain that information from another source, it may contact the physician/practitioner directly. It must notify the physician or practitioner that in order to refer or order services for a Medicare patient, the physician or practitioner must have an NPI.

If an opt-out physician/practitioner provides emergency or urgent care service to a beneficiary who has not signed a private contact with the physician or practitioner and the physician/practitioner submits an assigned claim, the physician or practitioner must complete Form CMS-855 and enroll in the Medicare program before receiving reimbursement. Under a similar circumstance, if the physician or practitioner submits an unassigned claim, the carrier must pay the beneficiary directly without requiring a

completed Form CMS-855. It may use the information from the affidavit to begin the enrollment process.

40.14 - Nonparticipating Physicians or Practitioners Who Opt Out of Medicare

(Rev. 1, 10-01-03)
B3-3044.14

A nonparticipating physician or practitioner may opt out of Medicare at any time in accordance with the following:

- The 2-year opt-out period begins the date the affidavit meeting the requirements of §40.9 is signed, provided the affidavit is filed within 10 days after the physician or practitioner signs his or her first private contract with a Medicare beneficiary.

- If the physician or practitioner does not timely file any required affidavit, the 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

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40.15 - Excluded Physicians and Practitioners

(Rev. 1, 10-01-03)
B3-3044.15

An excluded physician or practitioner may opt out of Medicare by submitting the required documentation in accordance with §40.9. When determining effective dates of the exclusion versus the opt-out, the date of exclusion always takes precedence over the date the physician or practitioner opts out of Medicare. A physician or practitioner who has been excluded must comply with 42 CFR 1001.1901, "Scope and Effect of Exclusion."

If an excluded/opt-out physician or practitioner submits a claim to Medicare, the carrier must not make payment for services furnished, ordered, or prescribed on or after the effective date of the exclusion.

The carrier must not make payment to a beneficiary who submits claims for services rendered by an excluded/opt-out physician or practitioner (except where payment would otherwise be made in accordance with the Medicare Program Integrity Manual). It must deny the claim and send the physician or practitioner the appropriate remittance and send the beneficiary a MSN as explained in §40.39.

40.16 - Relationship Between Opt-Out and Medicare Participation Agreements

(Rev. 1, 10-01-03)
B3-3044.16

Participation agreements will terminate on the opt out effective date. See 40.17 for effective date provisions. Physicians and practitioners may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. Nonparticipating physicians and practitioners may opt out at any time.

The carrier must updates carrier system files so that it may timely pay participating physicians and practitioners at the correct payment amounts in effect for that part of the fee schedule year before they opt out and to pay them as nonparticipating for emergency or urgent care as of their opt out effective date.

40.17 - Participating Physicians and Practitioners

(Rev. 1, 10-01-03)
B3-3044.17

Participating physicians and practitioners may opt out if they file an affidavit that meets the criteria and which is received by the carrier at least 30 days before the first day of the next calendar quarter showing an effective date of the first day in that quarter (i.e., January 1, April 1, July 1,October 1). They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit.

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The 30-day notice is required to allow sufficient time for the carrier to accomplish the appropriate system file updates before the effective date. The carrier must make participating physician status changes no less frequently than at the beginning of each calendar quarter. Therefore, participating physicians or practitioners must provide the carrier with 30 days notice that they intend to opt out at the beginning of the next calendar quarter.

Participating physicians or practitioners may sign private contracts only after the effective date of affidavits filed in accordance with §40.9. They may not provide services under private contracts with beneficiaries earlier than the effective date of the affidavit. It is necessary to treat nonparticipating physicians or practitioners differently from participating physicians or practitioners in order to assure that participating physicians or practitioners are paid properly for the services they furnish before the effective date of the affidavit.

Participating physicians or practitioners are paid at the full fee schedule for the services they furnish to Medicare beneficiaries. However, the law sets the payment amount for nonparticipating physicians or practitioners at 95 percent of the payment amount for participating physicians or practitioners.

Participating physicians or practitioners who opt out are treated as nonparticipating physicians or practitioners as of the effective date of the opt-out affidavit. When a participating physician/practitioner opts out of Medicare, the carrier must pay the

physician/practitioner at the higher participating physician/practitioner rate for services rendered in the period before the effective date of the opt-out; and at the nonparticipating rate for services rendered on and after the opt-out date.

40.18 - Physicians or Practitioners Who Choose to Opt Out of Medicare

(Rev. 1, 10-01-03)
B3-3044.18

If a physician/practitioner chooses to opt out of Medicare, it means that the physician/ practitioner opts out for all covered items and services that he or she furnishes. Physicians and practitioners cannot have private contracts that apply to some covered services they furnish but not to others. For example, if a physician or practitioner provides laboratory tests or durable medical equipment incident to his or her professional services and chooses to opt out of Medicare, then the physician/practitioner has opted out of Medicare for payment of lab services and Durable Medical Equipment, Prosthetics, and Orthotics (DMEPOS) as well as for professional services. If a physician or practitioner who has opted out refers a beneficiary to a non-opt-out physician or practitioner for medically necessary services, such as laboratory, DMEPOS or inpatient hospitalization, Medicare would cover those services.

In addition, because suppliers of DMEPOS, independent diagnostic testing facilities, clinical laboratories, etc., cannot opt out, the physician or practitioner owner of such suppliers cannot opt out as such a supplier. Therefore, the participating physician or practitioner becomes a nonparticipating physician or practitioner for purposes of Medicare payment for emergency and urgent care services on the effective date of the opt-out. (See §40.28).

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40.19 - Opt-Out Relationship to Noncovered Services

(Rev. 1, 10-01-03)
B3-3044.19

Because Medicare's rules do not apply to items or services that are categorically not covered by Medicare, a private contract is not needed to furnish such items or services to Medicare beneficiaries, and Medicare's claims filing rules and limits on charges do not apply to such items or services. For example, because Medicare does not cover hearing aids, a physician or practitioner, or other supplier, may furnish a hearing aid to a Medicare beneficiary and would not be required to file a claim with Medicare; further, the physician, practitioner, or other supplier would not be subject to any Medicare limit on the amount they could collect for the hearing aid.

If the item or service is one that is not categorically excluded from coverage by Medicare, but may be noncovered in a given case (for example, it is covered only where certain clinical criteria are met and there is a question as to whether the criteria are met), a non-opt-out physician/practitioner or other supplier is **not** relieved of his or her obligation to file a claim with Medicare. If the physician or practitioner or other supplier has given a

proper Advance Beneficiary Notice (ABN), they may collect from the beneficiary the full charge if Medicare does deny the claim.

Where a physician or practitioner has opted out of Medicare, he or she must provide covered services only through private contracts that meet the criteria specified in §40.8 (including items and services that are not categorically excluded from coverage but may be excluded in a given case). An opt-out physician or practitioner is prohibited from submitting claims to Medicare (except for emergency or urgent care services furnished to a beneficiary with whom the physician or practitioner did not have a private contract). (See §40.12.)

40.20 - Maintaining Information on Opt-Out Physicians

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

The carrier must maintain information on the opt-out physicians or practitioners. At a minimum, it must capture the name and National Provider Identifier (NPI) of the physician or practitioner, the effective date of the opt-out affidavit, and the end date of the opt-out period. The carrier may also include other provider-specific information it may need. If cost effective, it may house this information on its provider file.

40.21 - Informing Medicare Managed Care Plans of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 1, 10-01-03)
B3-3044.21

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The carrier must develop data exchange mechanisms for furnishing Medicare managed care plans in its service area with timely information on physicians and practitioners who have opted out of Medicare. For example, it may wish to establish an Internet Web site "Home Page" which houses all of the information on physicians or practitioners who have opted out. It will need to negotiate appropriate opt out information exchange mechanisms with each managed care plan in its service area.

40.22 - Informing the National Supplier Clearinghouse (NSC) of the Identity of the Opt-Out Physicians or Practitioners

(Rev. 1, 10-01-03)
B3-3044.22

The carrier must notify the NSC directly with timely information on physicians or practitioners who have opted out of Medicare. An Internet Web site "Home Page" is not an acceptable means of notifying the NSC. The NSC's address is as follows:

National Supplier Clearinghouse
P.O. Box 100142
Columbia, SC 29202-3142

40.23 - Organizations That Furnish Physician or Practitioner Services
(Rev. 1, 10-01-03)
B3-3044.23

The opt-out applies to all items or services the physician or practitioner furnishes to Medicare beneficiaries, regardless of the location where such items or services are furnished.

Where a physician or practitioner opts out and is a member of a group practice or otherwise reassigns his or her rights to Medicare payment to an organization, the organization may no longer bill Medicare or be paid by Medicare for services that the physician or practitioner furnishes to Medicare beneficiaries. However, if the physician or practitioner continues to grant the organization the right to bill and be paid for the services the physician or practitioner furnishes to patients, the organization may bill and be paid by the beneficiary for the services that are provided under the private contract. The decision of a physician or practitioner to opt out of Medicare does not affect the ability of the group practice or organization to bill Medicare for the services of physicians and practitioners who have not opted out of Medicare.

Corporations, partnerships, or other organizations that bill and are paid by Medicare for the services of physicians or practitioners who are employees, partners, or have other arrangements that meet the Medicare reassignment-of-payment rules cannot opt out because they are neither physicians nor practitioners. Of course, if every physician and practitioner within a corporation, partnership, or other organization opts out, then such corporation, partnership, or other organization would have, in effect, opted out.

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40.24 - The Difference Between Advance Beneficiary Notices (ABN) and Private Contracts
(Rev. 1, 10-01-03)
B3-3044.24

An Advance Beneficiary Notice (ABN) allows a beneficiary to make an informed consumer decision by knowing in advance that the beneficiary may have to pay out-of-pocket. An ABN is not needed where the item or service is categorically excluded from Medicare coverage or outside the scope of the benefit.

An ABN is used when the physician/practitioner believes that Medicare will not make payment, while private contracts are used for services that are covered by Medicare and for which payment might be made if a claim were to be submitted.

See the Medicare Claims Processing Manual, chapter 30, for a description of the ABN.

40.25 - Private Contracting Rules When Medicare is the Secondary Payer
(Rev. 1, 10-01-03)
B3-3044.25

The opt-out physician/practitioner must have a private contract with a Medicare beneficiary for all Medicare-covered services (see §40.7), notwithstanding that Medicare would be the secondary payer in a given situation. No Medicare primary **or** secondary payments will be made for items and services furnished by a physician/practitioner under the private contract.

40.26 - Registration and Identification of Physicians or Practitioners Who Opt Out

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

The carrier must use a National Provider Identifier (NPI) to identify opt-out physicians or practitioners nationwide.

40.27 - System Identification

(Rev. 1, 10-01-03)
B3-3044.27

The carrier must ensure that its system can automatically identify claims that include services furnished by providers or practitioners who have opted out of Medicare. It must not make payment to any opt-out physician/practitioner for items or services furnished on or after the effective date of the physician's or practitioner's opt out affidavit unless there are emergency or urgent care situations involved. In an emergency or urgent care situation, payment can be made for services furnished to a Medicare beneficiary if the beneficiary has no contract with the opt-out physician/practitioner. See the following section for related instructions.

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40.28 - Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)
B3-3044.28

Payment may be made for services furnished by an opt-out physician or practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician opted out.

Where a physician or a practitioner who has opted out of Medicare treats a beneficiary with whom the physician or practitioner does not have a private contract in an emergency or urgent situation, the physician or practitioner may not charge the beneficiary more than the Medicare limiting charge for the service and must submit the claim to Medicare on behalf of the beneficiary for the emergency or urgent care. Medicare payment may be made to the beneficiary for the Medicare covered services furnished to the beneficiary.

In other words, where the physician or practitioner provides emergency or urgent services to the beneficiary, the physician or practitioner must submit a claim to Medicare, and may collect no more than the Medicare limiting charge in the case of a physician, or the

deductible and coinsurance in the case of a practitioner. This implements §1802(b)(2)(A)(iii) of the Act, which specifies that the contract may not be entered into when the beneficiary is in need of emergency or urgent care. Because the services are excluded from coverage under §1862(a)(19) of the Act only if they are furnished under private contract, CMS concludes that they are not excluded in this case where there in no private contract, notwithstanding that they were furnished by an opt-out physician or practitioner. Hence, they are covered services furnished by a nonparticipating physician or practitioner, and the rules in effect absent the opt-out would apply in these cases. Specifically, the physician or practitioner may choose to take assignment (thereby agreeing to collect no more than the Medicare deductible and coinsurance based on the allowed amount from the beneficiary) or not to take assignment (and to collect no more than the Medicare limiting charge), but the practitioner must take assignment under §1842(b)(18) of the Act.

Therefore, in this circumstance the physician or practitioner must submit a completed Medicare claim on behalf of the beneficiary with the appropriate HCPCS code and HCPCS modifier that indicates the services furnished to the Medicare beneficiary were emergency or urgent and the beneficiary does not have a private agreement with the physician or practitioner. If the physician or practitioner did not submit **GJ** national HCPCS modifier, then the carrier must deny the claim so that the beneficiary can appeal.

GJ = Opt-out physician/practitioner EMERGENCY OR URGENT SERVICES

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This modifier must be used on claims for services rendered by an opt-out physician/ practitioner for an emergency/urgent service. The use of this modifier indicates that the service was furnished by an opt-out physician/practitioner who has not signed a private contract with a Medicare beneficiary for emergency or urgent care items and services furnished to, or ordered or prescribed for, such beneficiary on or after the date the physician/practitioner opted out.

The carrier must deny payment for emergency or urgent care items and services to both an opt-out physician or practitioner and the beneficiary if these parties have previously entered into a private contract, i.e., prior to the furnishing of the emergency or urgent care items or services but within the physician's or practitioner's opt out period.

Under the emergency and urgent care situation where an opt-out physician or practitioner renders emergency or urgent service to a Medicare beneficiary (e.g., a fractured leg) who has not entered into a private agreement with the physician or practitioner, as stated above the physician or practitioner is required to submit a claim to Medicare with the appropriate modifier (GJ and 54 as discussed further below) and is subject to all the rules and regulations of Medicare including limiting charge. However, if the opt-out physician or practitioner asks the beneficiary, with whom the physician or practitioner has no private contract, to return for a follow up visit (e.g., return within five to six weeks to remove the cast and examine the leg) the physician or practitioner must ask the beneficiary to sign a private contract. In other words, once a beneficiary no longer needs emergency or urgent care (i.e., nonurgent follow up care), Medicare cannot pay for the

follow up care and the physician or practitioner can and must, under the opt-out affidavit agreement, ask the beneficiary to sign a private agreement as a condition of further treatment.

The way this would work in the fractured leg example (see previous paragraph) is that the physician or practitioner would bill Medicare for the setting of the fractured leg with the emergency opt out CMS modifier **(GJ)** and the surgical care only modifier (54) to ensure that CMS does not pay the Evaluation and Management (E&M) that is in the global fee for the procedure. The physician or practitioner would then either have the beneficiary sign the private contract or refer the beneficiary to a Medicare physician or practitioner who would bill Medicare using the post op only modifier to be paid for the post op care in the global period.

If the beneficiary continues to be in a condition that requires emergency or urgent care (i.e., unconscious or unstable after surgery for an aneurysm) follow up care would continue to be paid under emergency or urgent care until such time as the beneficiary no longer needed such care. In the absence on controvertible evidence CMS recommends accepting what the physician or practitioner says via the modifiers and doing post-pay records review of frequent users of the opt-out modifier.

40.29 - Definition of Emergency and Urgent Care Situations

(Rev. 1, 10-01-03)
B3-3044.29

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Emergency services are defined as being services furnished to an individual who has an emergency medical condition as defined in 42 CFR 424.101. The CMS has adopted the definition of emergency medical condition in that section of the Code of Federal Regulations (CFR). However, it seemed clear that Congress intended that the term "emergency or urgent care services" not be limited to emergency services since they also included "urgent care services." Urgent Care Services are defined in 42 CFR 405.400 as services furnished within 12 hours in order to avoid the likely onset of an emergency medical condition. For example, if a beneficiary has an ear infection with significant pain, CMS would view that as requiring treatment to avoid the adverse consequences of continued pain and perforation of the eardrum. The patient's condition would not meet the definition of emergency medical condition because **immediate care** is not needed to avoid placing the health of the individual in serious jeopardy or to avoid serious impairment or dysfunction. However, although it does not meet the definition of emergency care, the beneficiary needs care within a relatively short period of time (which CMS defines as 12 hours) to avoid adverse consequences, and the beneficiary may not be able to find another physician or practitioner to provide treatment within 12 hours.

40.30 - Denial of Payment to Employers of Opt-Out Physicians and Practitioners

(Rev. 1, 10-01-03)
B3-3044.30

If an opt-out physician or practitioner is employed in a hospital setting and submits bills for which payment is prohibited, the Part B carrier usually detects and investigates the situation. However, in some instances an opt-out physician or practitioner may have a salary arrangement with a hospital or clinic or work in a group practice and may not directly submit bills for payment. If the carrier detects this situation, it must recover the payment made for the opt-out physician/practitioner from the hospital/clinic/group practice, after appropriate notification.

40.31 - Denial of Payment to Beneficiaries and Others

(Rev. 1, 10-01-03)
B3-3044.31

If a beneficiary submits a claim that includes items or services furnished by an opt-out physician or practitioner on dates on or after the effective date of opt out by such physician or practitioner, the carrier must deny such items or services. (See §40.6.) However, see §40.11 in cases in which the beneficiary appeals the denial on the basis that no private contract was signed.

40.32 - Payment for Medically Necessary Services Ordered or Prescribed by an Opt-out physician or Practitioner

(Rev. 1, 10-01-03)
B3-3044.32

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If claims are submitted for any items or services ordered or prescribed by an opt out physician or practitioner under §1802 of the Act, the carrier may pay for medically necessary services of the furnishing entity, provided the furnishing entity is not also a physician or practitioner that has opted out of the Medicare program.

40.33 - Mandatory Claims Submission

(Rev. 1, 10-01-03)
B3-3044.33

Section 1848(g)(4) of the Act, "Physician/Practitioner Submission of Claims," regarding mandatory claims submission, does not apply once a physician or practitioner signs and submits an affidavit to the Medicare carrier opting out of the Medicare program, for the duration of the physician's or practitioner's opt out period, unless the physician or practitioner knowingly and willfully violates a term of the affidavit.

40.34 - Renewal of Opt-Out

(Rev. 1, 10-01-03)
B3-3044.34

A physician or practitioner may renew an opt out without interruption by filing an affidavit with each carrier to which an affidavit was submitted for the first opt out (as specified in §40.9), and to each carrier to which a claim was submitted under §40.28

during the previous opt out period, provided the affidavits are filed within 30 days after the current opt-out period expires.

40.35 - Early Termination of Opt-Out

(Rev. 92; Issued: 06-27-08; Effective/Implementation Date: 09-29-08)

If a physician or practitioner changes his or her mind after the carrier has approved the affidavit, the opt-out may be terminated within 90 days of the effective date of the affidavit. To properly terminate an opt out, a physician or practitioner must:

- Not have previously opted out of Medicare;

- Notify all Medicare carriers, with which the physician or practitioner filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the opt-out period;

- Refund to each beneficiary with whom the physician or practitioner has privately contracted all payment collected in excess of:

  - The Medicare limiting charge (in the case of physicians or practitioners);or
  - The deductible and coinsurance (in the case of practitioners).

- Notify all beneficiaries with whom the physician or practitioner entered into private contracts of the physician's or practitioner's decision to terminate opt out and of the beneficiaries' rights to have claims filed on their behalf with Medicare for services furnished during the period between the effective date of the opt-out and the effective date of the termination of the opt-out period.

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When the physician or practitioner properly terminates opt-out in accordance with the second bullet above, the physician or practitioner (who was previously enrolled in Medicare) will be reinstated in Medicare as if there had been no opt-out, and the provision of §40.3 must not apply unless the physician or practitioner subsequently properly opts out.

40.36 - Appeals

(Rev. 1, 10-01-03)
B3-3044.36

A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, or failed to properly terminate opt-out is an initial determination for purposes of 42 CFR 405.803.

A determination by CMS that no payment can be made to a beneficiary for the services of a physician who has opted out is an initial determination for purposes of 42 CFR 405.803.

See the Medicare Claims Processing Manual, Chapter 29, "Appeals of Claims Decisions," for additional information on appeals.

40.37 - Application to Medicare+Choice Contracts

(Rev. 1, 10-01-03)
B3-3044.37

The Medicare Managed Care Manual contains instructions for M+C organizations about the impact on managed care.

The manual provides in general that M+C organizations:

- Must acquire and maintain information from Medicare carriers on physicians and practitioners who have opted out of Medicare.

- Must make no payment directly or indirectly for Medicare covered services furnished to a Medicare beneficiary by a physician or practitioner who has opted out of Medicare, except for emergency or urgent care services furnished to a beneficiary who has not previously entered into a private contract with the physician or practitioner, in accordance with §40.28.

The carrier must maintain mutually agreeable means of advising M+C organizations of who has opted out. Disputes with M+C organizations about the provision of opt out information should be referred to the regional office staff for resolution.

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40.38 - Claims Denial Notices to Opt-Out Physicians and Practitioners

(Rev. 1, 10-01-03)
B3-3044.38

To ensure that the notice denying payment to the opt-out physician or practitioner indicates the proper reason for denial of payment, the carrier must include language in the notice appropriate to particular circumstances as follows:

- When the claim is submitted **inadvertently** by the opt-out physician/practitioner, the carrier must use claim adjustment reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the remark code MA47:

  > Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment."

- The carrier uses the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner. It must use claim adjustment

reason code 28 (coverage not in effect at the time service was provided) at the claim level with group code PR (patient responsibility) and the claim level remark code MA56:

> Our records show that you have opted out of Medicare, agreeing with the patient not to bill Medicare for services/tests/supplies furnished. As a result, we cannot pay this claim. The patient is responsible for payment. Under Federal law you cannot charge more than the limiting charge amount.

40.39 - Claims Denial Notices to Beneficiaries

(Rev. 1, 10-01-03)
B3-3044.39

To ensure that the notice to the beneficiary indicates the proper reason for denial of payment, the carrier must include language in the notice appropriate to particular circumstances as follows:

- It must use the following MSN message when the claim is submitted **inadvertently** by the opt-out physician/practitioner:

  > MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

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- It must use the following message when the claim is submitted **knowingly and willfully** by the opt-out physician/practitioner:

  > MSN # 21.19 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge. Under Federal law your doctor cannot charge you more than the limiting charge amount."

- It must use the following message when the claim is submitted by the beneficiary for a service furnished by an opt-out physician/practitioner:

  > MSN # 21.20 - "The provider decided to drop out of Medicare. No payment can be made for this service. You are responsible for this charge."

40.40 - Reporting

(Rev. 108; Issued: 07-31-09; Effective: 01-01-10; Implementation: 01-04-10)

Contractors shall report quarterly physician and non-physician practitioner opt outs to CMS beginning with providers who have approved affidavits with opt out effective dates of January 1, 2010 through March 31, 2010 via the CROWD system. The data will be

entered into CROWD Form 8. Please refer to The Medicare Financial Management Manual, Publication 100-06, Chapter 6, Section 470 for complete instructions on how to enter data for quarterly opt out reporting.

The contractor shall maintain valid/approved affidavits in accordance with Section 40.9. The contractor must not count affidavits it receives for the opt out report that are invalid/not approved and must be returned to the physician/practitioner for clarification, incompleteness, etc. For the quarterly CROWD report, CMS only requires a count of the newly opted out physicians and non-physicians for the quarter. If no activity occurred, zeros will be entered for the report.

In CROWD contractors will report the number of providers who have opted out by specialty and quarter month. The quarter is based on a calendar year (e.g. for the first quarter, month # 1 (Jan), month # 2 (Feb) and month # 3 (Mar). No additional provider details (e.g., name, address, NPI) are required on the CROWD report. An example of the opt out reporting form in CROWD can be found in The Medicare Financial Management Manual, Publication 100-06, Chapter 6, Section 470.5.

Contractors shall also use CROWD to enter the total number of physicians and non-physician practitioners by specialty that it has on file to date flagged or identified as opt outs. For example, for specialty 01, the contractor would enter a number of all providers that have a status of opt out as of the close of the quarter.

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The CMS will no longer accept faxed, e-mailed or mailed copies of the opt out report.

The report is due in CROWD 30 days after the end of each quarter (e.g., a report for the quarter April1, 2010, through June 30, 2010, is due July 30, 2010.)

50 - Drugs and Biologicals

(Rev. 1, 10-01-03)
B3-2049, A3-3112.4.B, HO-230.4.B

The Medicare program provides limited benefits for outpatient drugs. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them.

Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals (see §50.1);
- They are of the type that are not usually self-administered. (see §50.2);
- They meet all the general requirements for coverage of items as incident to a physician's services (see §§50.1 and 50.3);

- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice (see §50.4);

- They are not excluded as noncovered immunizations (see §50.4.4.2); and

- They have not been determined by the FDA to be less than effective. (See §§50.4.4).

Medicare Part B does generally not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs. (See §110.3 for coverage of drugs, which are necessary to the effective use of Durable Medical Equipment (DME) or prosthetic devices.)

50.1 - Definition of Drug or Biological

(Rev. 1, 10-01-03)
B3-2049.1

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Drugs and biologicals must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (AOA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Combination drugs are also included in the definition of drugs if the combination itself or all of the therapeutic ingredients of the combination are included, or approved for inclusion, in any of the above drug compendia.

Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

50.2 - Determining Self-Administration of Drug or Biological

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

The Medicare program provides limited benefits for outpatient prescription drugs. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act to redefine this exclusion. The prior statutory language referred to those drugs "which cannot be self-administered." Implementation of the BIPA provision requires interpretation of the phrase "not usually self-administered by the patient".

A. Policy

Fiscal intermediaries, carriers and Medicare Administrative Contractors (MACs) are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. That is, if a drug is available in both oral and injectable forms, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

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B. Administered

The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the "incident to" benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

C. Usually

For the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

Reliable statistical information on the extent of self-administration by the patient may not always be available. Consequently, CMS offers the following guidance for each contractor's consideration in making this determination in the absence of such data:

1. Absent evidence to the contrary, presume that drugs delivered intravenously are not usually self-administered by the patient.

2. Absent evidence to the contrary, presume that drugs delivered by intramuscular injection are not usually self-administered by the patient. (Avonex, for example, is delivered by intramuscular injection, not usually self-administered by the patient.) The contractor may consider the depth and nature of the particular intramuscular injection in applying this presumption. In applying this presumption, contractors should examine the use of the particular drug and consider the following factors:

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3. Absent evidence to the contrary, presume that drugs delivered by subcutaneous injection are self-administered by the patient. However, contractors should examine the use of the particular drug and consider the following factors:

> A. **Acute Condition -** Is the condition for which the drug is used an acute condition? If so, it is less likely that a patient would self-administer the drug. If the condition were longer term, it would be more likely that the patient would self-administer the drug.
>
> **B. Frequency of Administration -** How often is the injection given? For example, if the drug is administered once per month, it is less likely to be self-administered by the patient. However, if it is administered once or more per week, it is likely that the drug is self-administered by the patient.

In some instances, carriers may have provided payment for one or perhaps several doses of a drug that would otherwise not be paid for because the drug is usually self-administered. Carriers may have exercised this discretion for limited coverage, for example, during a brief time when the patient is being trained under the supervision of a physician in the proper technique for self-administration. Medicare will no longer pay for such doses. In addition, contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.

D. Definition of Acute Condition

For the purposes of determining whether a drug is usually self-administered, an acute condition means a condition that begins over a short time period, is likely to be of short duration and/or the expected course of treatment is for a short, finite interval. A course of treatment consisting of scheduled injections lasting less than 2 weeks, regardless of frequency or route of administration, is considered acute. Evidence to support this may include Food and Drug Administration (FDA) approval language, package inserts, drug compendia, and other information.

E. By the Patient

The term "by the patient" means Medicare beneficiaries as a collective whole. The carrier includes only the patients themselves and not other individuals (that is, spouses, friends, or other care-givers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The carrier ignores all instances when the drug is administered on an inpatient basis.

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The carrier makes this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis. In evaluating whether beneficiaries as a collective whole self-administer, individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for "self-administered by the patient" was based; for example, an early onset of dementia.

F. Evidentiary Criteria

Contractors are only required to consider the following types of evidence: peer reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA approved label, and package inserts. Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

Contractors should also use these evidentiary criteria when reviewing requests for making a determination as to whether a drug is usually self-administered, and requests for reconsideration of a pending or published determination.

Note that prior to August 1, 2002, one of the principal factors used to determine whether a drug was subject to the self-administered exclusion was whether the FDA label

contained instructions for self-administration. However, CMS notes that under the new standard, the fact that the FDA label includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to this exclusion.

G. Provider Notice of Noncovered Drugs

Contractors must describe on their Web site the process they will use to determine whether a drug is usually self-administered and thus does not meet the "incident to" benefit category. Contractors must publish a list of the injectable drugs that are subject to the self-administered exclusion on their Web site, including the data and rationale that led to the determination. Contractors will report the workload associated with developing new coverage statements in CAFM 21208.

Contractors must provide notice 45 days prior to the date that these drugs will not be covered. During the 45-day time period, contractors will maintain existing medical review and payment procedures. After the 45-day notice, contractors may deny payment for the drugs subject to the notice.

Contractors must not develop local coverage determinations (LCDs) for this purpose because further elaboration to describe drugs that do not meet the 'incident to' and the 'not usually self-administered' provisions of the statute are unnecessary. Current LCDs based solely on these provisions must be withdrawn. LCDs that address the self-administered exclusion and other information may be reissued absent the self-administered drug exclusion material. Contractors will report this workload in CAFM 21206. However, contractors may continue to use and write LCDs to describe reasonable and necessary uses of drugs that are not usually self-administered.

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H. Conferences Between Contractors

Contractors' Medical Directors may meet and discuss whether a drug is usually self-administered without reaching a formal consensus. Each contractor uses its discretion as to whether or not it will participate in such discussions. Each contractor must make its own individual determinations, except that fiscal intermediaries may, at their discretion, follow the determinations of the local carrier with respect to the self-administered exclusion.

I. Beneficiary Appeals

If a beneficiary's claim for a particular drug is denied because the drug is subject to the "self-administered drug" exclusion, the beneficiary may appeal the denial. Because it is a "benefit category" denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A "benefit category" denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.

J. Provider and Physician Appeals

A physician accepting assignment may appeal a denial under the provisions found in Pub. 100-04, Medicare Claims Processing Manual, chapter 29.

K. Reasonable and Necessary

Contractors will make the determination of reasonable and necessary with respect to the medical appropriateness of a drug to treat the patient's condition. Contractors will continue to make the determination of whether the intravenous or injection form of a drug is appropriate as opposed to the oral form. Contractors will also continue to make the determination as to whether a physician's office visit was reasonable and necessary. However, contractors should not make a determination of whether it was reasonable and necessary for the patient to choose to have his or her drug administered in the physician's office or outpatient hospital setting. That is, while a physician's office visit may not be reasonable and necessary in a specific situation, in such a case an injection service would be payable.

L. Reporting Requirements

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Each carrier, intermediary and Medicare Administrative Contractor (MAC) must report to CMS its complete list of injectable drugs that the contractor has determined are excluded when furnished incident to a physician's service on the basis that the drug is usually self-administered. The CMS expects that contractors will review injectable drugs on a rolling basis and update their list of excluded drugs as it is developed and no less frequently than annually. For example, contractors should not wait to publish this list until every drug has been reviewed. Contractors must enter their self-administered drug exclusion list to the Medicare Coverage Database (MCD). This database can be accessed at www.cms.hhs.gov/mcd. See Pub.100-08, Medicare Program Integrity Manual, Chapter 3, Section 3.3, *"Policies and Guidelines Applied During Review"*, for instructions on submitting these lists to the MCD.

M. Drugs Treated as Hospital Outpatient Supplies

In certain circumstances, Medicare pays for drugs that may be considered usually self-administered by the patient when such drugs function as supplies. This is the case when the drugs provided are an integral component of a procedure or are directly related to it, i.e., when they facilitate the performance of or recovery from a particular procedure. Except for the applicable copayment, hospitals may not bill beneficiaries for these types of drugs because their costs, as supplies, are packaged into the payment for the procedure with which they are used. Listed below are examples of when drugs are treated as supplies and hospitals should bill Medicare for the drug as a supply and should not separately bill the beneficiary.

- *Sedatives administered to a patient while he or she is in the preoperative area being prepared for a procedure.*

- *Mydriatic drops instilled into the eye to dilate the pupils, anti-inflammatory drops, antibiotic drops/ointments, and ocular hypotensives that are administered to a patient immediately before, during, or immediately following an ophthalmic procedure. This does not refer to the patient's eye drops that the patient uses pre- and postoperatively.*

- *Barium or low osmolar contrast media provided integral to a diagnostic imaging procedure.*

- *Topical solution used with photodynamic therapy furnished at the hospital to treat nonhyperkeratotic actinic keratosis lesions of the face or scalp.*

- *Antibiotic ointments such as bacitracin, placed on a wound or surgical incision at the completion of a procedure.*

The following are examples of when a drug is not directly related or integral to a procedure, and does not facilitate the performance of or recovery from a procedure. Therefore the drug is not considered a packaged supply. In many of these cases the drug itself is the treatment instead of being integral or directly related to the procedure, or facilitating the performance of or recovery from a particular procedure.

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- *Drugs given to a patient for his or her continued use at home after leaving the hospital.*

- *Oral pain medication given to an outpatient who develops a headache while receiving chemotherapy administration treatment.*

- *Daily routine insulin or hypertension medication given preoperatively to a patient.*

- *A fentanyl patch or oral pain medication such as hydrocodone, given to an outpatient presenting with pain.*

- *A laxative suppository for constipation while the patient waits to receive an unrelated X-ray.*

These two lists of examples may serve to guide hospitals in deciding which drugs are supplies packaged as a part of a procedure, and thus may be billed under Part B. Hospitals should follow CMS' guidance for billing drugs that are packaged and paid as supplies, reporting coded and uncoded drugs with their charges under the revenue code associated with the cost center under which the hospital accumulates the costs for the drugs.

50.3 - Incident To Requirements

(Rev. 1, 10-01-03)

B3-2049.3

In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:

- Be of a form that is not usually self-administered;
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological must be included in the physician's bill, and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements. (See §§170, 180, 190 and 200 for specific instructions.)

Whole blood is a biological, which cannot be self-administered and is covered when furnished incident to a physician's services. Payment may also be made for blood fractions if all coverage requirements are satisfied and the blood deductible has been met.

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50.4 - Reasonableness and Necessity

(Rev. 1, 10-01-03)
B3-2049.4

50.4.1 - Approved Use of Drug

(Rev. 1, 10-01-03)
B3-2049.4

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20.) Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, the program may pay for the use of an FDA approved drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

The carrier, DMERC, or intermediary will deny coverage for drugs and biologicals, which have not received final marketing approval by the FDA unless it receives instructions from CMS to the contrary. For specific guidelines on coverage of Group C cancer drugs, see the Medicare National Coverage Determinations Manual.

If there is reason to question whether the FDA has approved a drug or biological for marketing, the carrier or intermediary must obtain satisfactory evidence of FDA's approval. Acceptable evidence includes:

- A copy of the FDA's letter to the drug's manufacturer approving the new drug application (NDA);
- A listing of the drug or biological in the FDA's "Approved Drug Products" or "FDA Drug and Device Product Approvals";
- A copy of the manufacturer's package insert, approved by the FDA as part of the labeling of the drug, containing its recommended uses and dosage, as well as possible adverse reactions and recommended precautions in using it; or
- Information from the FDA's Web site.

When necessary, the regional office (RO) may be able to help in obtaining information.

50.4.2 - Unlabeled Use of Drug

(Rev. 1, 10-01-03)
B3-2049.3

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An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. In the case of drugs used in an anti-cancer chemotherapeutic regimen, unlabeled uses are covered for a medically accepted indication as defined in §50.5.

These decisions are made by the contractor on a case-by-case basis.

50.4.3 - Examples of Not Reasonable and Necessary

(Rev. 1, 10-01-03)
B3-2049.4

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice:

1. Not for Particular Illness

Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations). Charges for medications, e.g., vitamins, given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.

2. Injection Method Not Indicated

Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. Carriers exclude the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.

3. Excessive Medications

Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered. For example, the accepted standard of medical practice in the maintenance treatment of pernicious anemia is one vitamin B-12 injection per month. Carriers exclude the entire charge for injections given in excess of this frequency unless there are special medical circumstances that justify additional injections.

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Carriers will supplement the guidelines as necessary with guidelines concerning appropriate use of specific injections in other situations. They will use the guidelines to screen out questionable cases for special review, further development, or denial when the injection billed for would not be reasonable and necessary. They will coordinate any type of drug treatment review with the Quality Improvement Organization (QIO).

If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the carrier excludes the entire charge (i.e., for both the drug and its administration). Also, carriers exclude from payment any charges for other services (such as office visits) which were primarily for the purpose of administering a noncovered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

50.4.4 - Payment for Antigens and Immunizations
(Rev. 1, 10-01-03)

50.4.4.1 - Antigens
(Rev. 1, 10-01-03)
B3-2049.4

Payment may be made for a reasonable supply of antigens that have been prepared for a particular patient if: (1) the antigens are prepared by a physician who is a doctor of

medicine or osteopathy, and (2) the physician who prepared the antigens has examined the patient and has determined a plan of treatment and a dosage regimen.

Antigens must be administered in accordance with the plan of treatment and by a doctor of medicine or osteopathy or by a properly instructed person (who could be the patient) under the supervision of the doctor. The associations of allergists that CMS consulted advised that a reasonable supply of antigens is considered to be not more than a 12-month supply of antigens that has been prepared for a particular patient at any one time. The purpose of the reasonable supply limitation is to assure that the antigens retain their potency and effectiveness over the period in which they are to be administered to the patient. (See §§20.2 and 50.2.)

50.4.4.2 - Immunizations

(Rev. 145, Issued: 07-08-11, Effective: 08-08-11, Implementation: 08-08-11)

Vaccinations or inoculations are excluded as immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as anti-rabies treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin. In the absence of injury or direct exposure, preventive immunization (vaccination or inoculation) against such diseases as smallpox, polio, diphtheria, etc., is not covered. However, pneumococcal, hepatitis B, and influenza virus vaccines are exceptions to this rule. (See items A, B, and C below.) In cases where a vaccination or inoculation is excluded from coverage, related charges are also not covered.

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A. Pneumococcal Pneumonia Vaccinations

Effective for services furnished on or after May 1, 1981, the Medicare Part B program covers pneumococcal pneumonia vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. This includes revaccination of patients at highest risk of pneumococcal infection. Typically, these vaccines are administered once in a lifetime except for persons at highest risk. Effective July 1, 2000, Medicare does not require for coverage purposes that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

An initial vaccine may be administered only to persons at high risk (see below) of pneumococcal disease. Revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least 5 years have [passed since the previous dose of pneumococcal vaccine.

Persons at high risk for whom an initial vaccine may be administered include all people age 65 and older; immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular disease,

pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks); and individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

Persons at highest risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. It is not appropriate for routine revaccination of people age 65 or older that are not at highest risk.

Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable to rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about his or her vaccination history in the past 5 years, the vaccine should be given. However, if the patient is certain he/she was were vaccinated in the last 5 years, the vaccine should not be given. If the patient is certain that the vaccine was given more than 5 years ago, revaccination is covered only if the patient is at high risk.

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B. Hepatitis B Vaccine

Effective for services furnished on or after September 1, 1984, P.L. 98-369 provides coverage under Part B for hepatitis B vaccine and its administration, furnished to a Medicare beneficiary who is at high or intermediate risk of contracting hepatitis B. This coverage is effective for services furnished on or after September 1, 1984. High-risk groups currently identified include (see exception below):

- ESRD patients;
- Hemophiliacs who receive Factor VIII or IX concentrates;
- Clients of institutions for the mentally retarded;
- Persons who live in the same household as a Hepatitis B Virus (HBV) carrier;
- Homosexual men; and
- Illicit injectable drug abusers.

Intermediate risk groups currently identified include:

- Staff in institutions for the mentally retarded; and

- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

EXCEPTION: Persons in both of the above-listed groups in paragraph B, would not be considered at high or intermediate risk of contracting hepatitis B, however, if there were laboratory evidence positive for antibodies to hepatitis B. (ESRD patients are routinely tested for hepatitis B antibodies as part of their continuing monitoring and therapy.)

For Medicare program purposes, the vaccine may be administered upon the order of a doctor of medicine or osteopathy, by a doctor of medicine or osteopathy, or by home health agencies, skilled nursing facilities, ESRD facilities, hospital outpatient departments, and persons recognized under the incident to physicians' services provision of law.

A charge separate from the ESRD composite rate will be recognized and paid for administration of the vaccine to ESRD patients.

C. Influenza Virus Vaccine

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Effective for services furnished on or after May 1, 1993, the Medicare Part B program covers influenza virus vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. Typically, these vaccines are administered once a flu season. Medicare does not require, for coverage purposes, that a doctor of medicine or osteopathy order the vaccine. Therefore, the beneficiary may receive the vaccine upon request without a physician's order and without physician supervision.

50.4.5 - Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

(Rev. 96, Issued: 10-24-08, Effective: 06-05-08 NCCN/06-10-08 Thomson Micromedex/07-02-08 Clinical Pharmacology, Implementation: 11-25-08)

A. Overview

Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below. A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer. Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. The contractor may maintain its own subscriptions to the listed compendia or peer-reviewed publications to determine the medically accepted indication of drugs or biologicals used off-label in an anti-cancer chemotherapeutic regimen. Compendia documentation or

peer-reviewed literature supporting off-label use by the treating physician may also be requested of the physician by the contractor.

B. Recent Revisions to the Compendia List

Do not deny coverage based solely on the absence of FDA-approved labeling for the use, if the use is supported by any of the following compendia and the use is **not** listed as unsupported, not indicated, not recommended, or equivalent terms, in any of the following compendia:

Existing - American Hospital Formulary Service-Drug Information (AHFS-DI)

Effective June 5, 2008 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium

Effective June 10, 2008 - Thomson Micromedex DrugDex

Effective July 2, 2008 - Clinical Pharmacology

The listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium. In general, a use is identified by a compendium as **medically accepted** if the:

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1. indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,

2. narrative text in AHFS-DI or Clinical Pharmacology is supportive.

A use is **not medically accepted** by a compendium if the:

1. indication is a Category 3 in NCCN or a Class III in DrugDex; or,

2. narrative text in AHFS or Clinical Pharmacology is "not supportive."

The complete absence of narrative text on a use is considered neither supportive nor non-supportive.

C. Use Supported by Clinical Research That Appears in Peer-Reviewed Medical Literature

Contractors may also identify off-label uses that are supported by clinical research under the conditions identified in this section. Peer-reviewed medical literature may appear in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication. In-house publications of entities whose business relates to the manufacture, sale, or distribution of pharmaceutical

products are excluded from consideration. Abstracts (including meeting abstracts) are excluded from consideration.

In determining whether an off-label use is supported, the contractors will evaluate the evidence in published, peer-reviewed medical literature listed below. When evaluating this literature, they will consider (among other things) the following:

- Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence
- Whether the administered chemotherapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question. The contractor will consider:

1. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);

2. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,

3. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

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The contractor will use peer-reviewed medical literature appearing in the regular editions of the following publications, not to include supplement editions privately funded by parties with a vested interest in the recommendations of the authors:

American Journal of Medicine;

Annals of Internal Medicine;

Annals of Oncology;

Annals of Surgical Oncology;

Biology of Blood and Marrow Transplantation;

Blood;

Bone Marrow Transplantation;

British Journal of Cancer;

British Journal of Hematology;

British Medical Journal;

Cancer;

Clinical Cancer Research;

Drugs;

European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);

Gynecologic Oncology;

International Journal of Radiation, Oncology, Biology, and Physics;

The Journal of the American Medical Association;

Journal of Clinical Oncology;

Journal of the National Cancer Institute;

Journal of the National Comprehensive Cancer Network (NCCN);

Journal of Urology;

Lancet;

Lancet Oncology;

Leukemia;

The New England Journal of Medicine; or

Radiation Oncology

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D. Generally

FDA-approved drugs and biologicals may also be considered for use in the determination of medically accepted indications for off-label use if determined by the contractor to be reasonable and necessary.

If a use is identified as not indicated by the Centers for Medicare and Medicaid Services (CMS) or the FDA, or if a use is specifically identified as not indicated in one or more of the compendia listed, or if the contractor determines, based on peer-reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered.

50.4.5.1 - Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

(Rev. 120, Issued: 01-29-10, Effective:01-01-10, Implementation: 03-01-10)

A. Background

In the Physician Fee Schedule final rule for calendar year (CY) 2008, the CMS established a process for revising the list of compendia, as authorized under section 1861(t)(2) of the Social Security Act, and also established a definition for "compendium." At 42 CFR 414.930(a), a compendium is defined "as a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example, a compendium of anti-cancer treatment." A compendium: (1) includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases; (2) is indexed by drug or biological, and, (3) effective January 1, 2010, pursuant to section 182(b) of the Medicare Improvements for Patients and Providers Act (MIPPA), has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests. See 42 CFR 414.930(a); 72 FR 66222, 66404, and 74 FR 61901.

B. Desirable Characteristics of Compendia

CMS increased the transparency of the process by incorporating a list of desirable compendium characteristics outlined by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) as criteria for decision-making. The list of desirable compendium characteristics was developed by the MedCAC during a public session on March 30, 2006. T he goal of this session was to review the evidence and advise CMS on the desirable characteristics of compendia for use in the determination of medically accepted indications of drugs and biologicals in anti-cancer therapy. As a result of this meeting, the MedCAC generated the following list of desirable characteristics:

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- Extensive breadth of listings,
- Quick processing from application for inclusion to listing,
- Detailed description of the evidence reviewed for every individual listing,
- Use of pre-specified published criteria for weighing evidence,
- Use of prescribed published process for making recommendations,
- Publicly transparent process for evaluating therapies,
- Explicit "Not Recommended" listing when validated evidence is appropriate,
- Explicit listing and recommendations regarding therapies, including sequential use or combination in relation to other therapies,
- Explicit "Equivocal" listing when validated evidence is equivocal, and,
- Process for public identification and notification of potential conflicts of interest of the compendias' parent and sibling organizations, reviewers, and committee members, with an established procedure to manage recognized conflicts.

Furthermore, the provisions discussed in section 182(b) of MIPPA bring more uniformity in compendia conflict of interest disclosure practices and allow the public the ability to monitor how these policies impact compendia off-label recommendations.

C. Process for Changing List of Compendia

CMS will provide an annual 30-day open request period starting January 15 for the public to submit requests for additions or deletions to the compendia list contained on the CMS Web site at http://www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp.

Complete requests as defined in section 50.4.5.1.D will be posted to the Web site annually by March 15 for public notice and comment. The request will identify the requestor and the requested action CMS is being asked to make to the list. Public comments will be accepted for a 30-day period beginning on the day the request is posted on the Web site. In addition to the annual process, CMS may generate a request for changes to the list at any time an urgent action is needed to protect the interests of the Medicare program and its beneficiaries.

D. Content of Requests

For a request to be considered complete, and therefore accepted for review, it must include the following information:

- The full name and contact information (including the mailing address, e-mail address, and telephone number) of the requestor. If the requestor is not an individual person, the information shall identify the officer or other representative who is authorized to act for the requestor on all matters related to the request.

- Full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

- A complete, written copy of the compendium that is the subject of the request. If the complete compendium is available electronically, it may be submitted electronically in place of hard copy. If the compendium is available online, the requestor may provide CMS with electronic access by furnishing at no cost to the Federal Government sufficient accounts for the purposes and duration of the review of the application in place of hard copy.

- The specific action that the requestor wishes CMS to take, for example to add or delete a specific compendium.

- Detailed, specific documentation that the compendium that is the subject of the request does or does not comply with the conditions of this rule. Broad, nonspecific claims without supporting documentation cannot be efficiently reviewed; therefore, they will not be accepted.

- A publicly transparent process for evaluating therapies, which includes the following: (1) internal or external request for listing of a therapy recommendation,

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including criteria used to evaluate the request (the complete application), (2) listing of all the evidentiary materials reviewed or considered for inclusion in the compendium (3) listing of all individuals who substantively participated in the review and development of the request, and (4) minutes and voting records of meetings for the review and disposition of the request. The information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication.

- A publicly transparent process for identifying potential conflicts of interests that provides: (1) direct or indirect financial relationships, and (2) ownership or investment interests that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations, and the manufacturer or seller of the drug or biological being reviewed by the compendium. This information shall be identified and made timely available in response to a public request for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication.

A request may have only a single compendium as its subject. This will provide greater clarity to the scope of the Agency's review of a given request. A requestor may submit multiple requests, each requesting a different action.

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E. Submission of Requests

Requests must be in writing and submitted in one of the following two ways (no duplicates please):

1. Electronic requests are encouraged to facilitate administrative efficiency. Each solicitation will include the electronic address for submissions.

2. Hard copy requests can be sent to: Centers for Medicare & Medicaid Services, Coverage and Analysis Group, Mailstop C1–09–06, 7500 Security Boulevard, Baltimore, MD 21244.

Allow sufficient time for hard copies to be received prior to the close of the open request period.

F. Review of Requests

CMS will consider a compendium's attainment of the desirable characteristics specified in 50.4.5.1.B when reviewing requests. CMS may consider additional, reasonable factors in making a determination. For example, CMS may consider factors that are likely to impact the compendium's suitability for this use, such as a change in the compendium's

ownership or affiliation, and the standards applicable to the evidence considered by the compendium. CMS may consider that broad accessibility by the general public to the information contained in the compendium may assist beneficiaries, their treating physicians, or both, in choosing among treatment options. CMS will also consider a compendium's grading of evidence used in making recommendations regarding off-label uses, and the process by which the compendium grades the evidence. CMS may, at its discretion, combine and consider multiple requests that refer to the same compendium, even if those requests are for different actions. This facilitates administrative efficiency in the review of requests.

G. Publishing Review Results

CMS will publish decisions on the CMS Web site within 90 days after the close of the public comment period.

(This instruction was last reviewed by CMS in December 2009.)

50.4.6 - Less Than Effective Drug

(Rev. 1, 10-01-03)
B3-2049.4.C.5

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This is a drug that has been determined by the Food and Drug Administration (FDA) to lack substantial evidence of effectiveness for all labeled indications. Also, a drug that has been the subject of a Notice of an Opportunity for a Hearing (NOOH) published in the "Federal Register" before being withdrawn from the market, and for which the Secretary has not determined there is a compelling justification for its medical need, is considered less than effective. This includes any other drug product that is identical, similar, or related. Payment may not be made for a less than effective drug.

Because the FDA has not yet completed its identification of drug products that are still on the market, existing FDA efficacy decisions must be applied to all similar products once they are identified.

50.4.7 - Denial of Medicare Payment for Compounded Drugs Produced in Violation of Federal Food, Drug, and Cosmetic Act

(Rev. 1, 10-01-03)
B3-2049.4.C.6

The Food and Drug Administration (FDA) has found that, from time to time, firms established as retail pharmacies engage in mass production of compounded drugs, beyond the normal scope of pharmaceutical practice, in violation of the Federal Food, Drug, and Cosmetic Act (FFDCA). By compounding drugs on a large scale, a company may be operating as a drug manufacturer within the meaning of the FFDCA, without complying with requirements of that law. Such companies may be manufacturing drugs, which are subject to the new drug application (NDA) requirements of the FFDCA, but for which FDA has not approved an NDA or which are misbranded or adulterated. If the FDA has

not approved the manufacturing and processing procedures used by these facilities, the FDA has no assurance that the drugs these companies are producing are safe and effective. The safety and effectiveness issues pertain to such factors as chemical stability, purity, strength, bioequivalency, and biovailability.

Section 1862(a)(1)(A) of the Act requires that drugs must be reasonable and necessary in order to by covered under Medicare. This means, in the case of drugs, the FDA must approve them for marketing. Section 50.4.1 instructs carriers and intermediaries to deny coverage for drugs that have not received final marketing approval by the FDA, unless instructed otherwise by CMS. The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §180, instructs carriers to deny coverage of services related to the use of noncovered drugs as well. Hence, if DME or a prosthetic device is used to administer a noncovered drug, coverage is denied for both the nonapproved drug and the DME or prosthetic device.

In those cases in which the FDA has determined that a company is producing compounded drugs in violation of the FFDCA, Medicare does not pay for the drugs because they do not meet the FDA approval requirements of the Medicare program. In addition, Medicare does not pay for the DME or prosthetic device used to administer such a drug if FDA determines that a required NDA has not been approved or that the drug is misbranded or adulterated.

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The CMS will notify the carrier when the FDA has determined that compounded drugs are being produced in violation of the FFDCA. The carrier does not stop Medicare payment for such a drug unless it is notified that it is appropriate to do so through a subsequent instruction. In addition, if the carrier or Regional Offices (ROs) become aware that other companies are possibly operating in violation of the FFDCA, the carrier or RO notifies:

Centers for Medicare & Medicaid Services
Center for Medicare Management
7500 Security Blvd.
Baltimore, MD 21244-1850

50.4.8 - Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

50.5 - Self-Administered Drugs and Biologicals

(Rev. 1, 10-01-03)
B3-2049.5

Medicare Part B does not cover drugs that are usually self-administered by the patient unless the statute provides for such coverage. The statute explicitly provides coverage, for blood clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, certain oral anti-cancer drugs and anti-emetics used in certain situations.

50.5.1 - Immunosuppressive Drugs
(Rev. 1, 10-01-03)
A3-3112.4.B.3, HO-230.4.B.3, AB-01-10

Until January 1, 1995, immunosuppressive drugs were covered under Part B for a period of one year following discharge from a hospital for a Medicare covered organ transplant. The CMS interpreted the 1-year period after the date of the transplant procedure to mean 365 days from the day on which an inpatient is discharged from the hospital. Beneficiaries are eligible to receive additional Part B coverage **within** 18 months after the discharge date for drugs furnished in 1995; **within** 24 months for drugs furnished in 1996; **within** 30 months for drugs furnished in 1997; and **within** 36 months for drugs furnished after 1997.

For immunosuppressive drugs furnished on or after December 21, 2000, this time limit for coverage is eliminated.

Covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. (This is an exception to the standing drug policy which permits coverage of FDA approved drugs for **nonlabeled** uses, where such uses are found to be reasonable and necessary in an individual case.)

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Covered drugs also include those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. Therefore, antibiotics, hypertensives, and other drugs that are not directly related to rejection are not covered.

The FDA has identified and approved for marketing the following specifically labeled immunosuppressive drugs. They are:

Sandimmune (cyclosporine), Sandoz Pharmaceutical;
Imuran (azathioprine), Burroughs Wellcome;
Atgam (antithymocyte globulin), Upjohn;
Orthoclone OKT3 (Muromonab-CD3), Ortho Pharmaceutical;
Prograf (tacrolimus), Fujisawa USA, Inc;
Celicept (mycophenolate mefetil, Roche Laboratories;
Daclizumab (Zenapax);
Cyclophosphamide (Cytoxan);
Prednisone; and
Prednosolone.

The CMS expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.

50.5.2 - Erythropoietin (EPO)
(Rev. 1, 10-01-03)
A3-3112.4.B.4, HO-230.4.B.4

The statute provides that EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis. Coverage is available regardless of whether the drug is administered by the patient or the patient's caregiver. EPO is a biologically engineered protein which stimulates the bone marrow to make new red blood cells.

NOTE: Non-ESRD patients who are receiving EPO to treat anemia induced by other conditions such as chemotherapy or the drug zidovudine (commonly called AZT) must meet the coverage requirements in §50.

EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis when:

- It is administered in the renal dialysis facility; or

- It is self-administered in the home by any dialysis patient (or patient caregiver) who is determined competent to use the drug and meets the other conditions detailed below.

NOTE: Payment may not be made for EPO under the incident to provision when EPO is administered in the renal dialysis facility.

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Also, in the office setting, reimbursement will be made for the administration charge only for non-ESRD patients receiving EPO.

50.5.2.1 - Requirements for Medicare Coverage for EPO
(Rev. 1, 10-01-03)
B3-2049.5

Medicare covers EPO and items related to its administration for dialysis patients who use EPO in the home when the following conditions are met:

A. Patient Care Plan

A dialysis patient who uses EPO in the home must have a current care plan (a copy of which must be maintained by the designated backup facility for Method II patients) for monitoring home use of EPO that includes the following:

1. Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload;

2. Review of medications to ensure adequate provision of supplemental iron;

3. Ongoing evaluations of hematocrit and iron stores;

4. Reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;

5. Method for physician and facility (including backup facility for Method II patients) follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;

6. Training of the patient to identify the signs and symptoms of hypotension and hypertension; and

7. The decrease or discontinuance of EPO if hypertension is uncontrollable.

B. Patient Selection

The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

1. Preselection Monitoring

The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.

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2 Conditions the Patient Must Meet

The assessment must find that the patient meets the following conditions:

a. Is a dialysis patient;

b. Has a hematocrit (or comparable hemoglobin level) that is as follows:

- For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. Patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.

- For a patient who has been receiving EPO from the facility or the physician, between 30 and 36 percent.

c. Is under the care of:

- A physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and

- A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.

3. The assessment must find that the patient or a caregiver meets the following conditions:

- Is trained by the facility to inject EPO and is capable of carrying out the procedure;

- Is capable of reading and understanding the drug labeling; and

- Is trained in, and capable of observing, aseptic techniques.

4. Care and Storage of Drug

The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

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C. Responsibilities of Physician or Dialysis Facility

The patient's physician or dialysis facility must:

- Develop a protocol that follows the drug label instructions;

- Make the protocol available to the patient to ensure safe and effective home use of EPO;

- Through the amounts prescribed, ensure that the drug on hand at any time does not exceed a 2-month supply;

- Maintain adequate records to allow quality assurance for review by the Network and State Survey Agencies. For Method II patients, current records must be provided to and maintained by the designated backup facility; and

- The dialysis facility must submit claims for EPO, if the facility provides it.

See the Medicare Claims Processing Manual, Chapter 11, "End Stage Renal Disease," for instructions for billing and processing claims for EPO under Method 1 and Method 2. Note that hematocrit readings are required on claims. It is expected that the ESRD facility or hospital outpatient department will maintain the following information in each patient's medical record to permit the review of the medical necessity of EPO.

1. Diagnostic coding;
2. Most recent creatinine prior to initiation of EPO therapy;
3. Date of most recent creatinine prior to initiation of EPO therapy;
4. Most recent hematocrit (HCT) prior to initiation of EPO therapy;
5. Date of most recent hematocrit (HCT) prior to initiation of EPO therapy;
6. Dosage in units/kg;
7. Weight in kgs; and
8. Number of units administered.

50.5.2.2 - Medicare Coverage of Epoetin Alfa (Procrit) for Preoperative Use

(Rev. 1, 10-01-03)
PM-AB-99-59, Dated 8/1/99

This instruction pertains exclusively to the preoperative surgical indication of the drug Procrit, in which it is administered to specific patients prior to surgery to reduce risk of transfusion. It does not affect Medicare policies related to other Food and Drug Administration (FDA) approved uses of Procrit. **It is not a national coverage decision**.

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Procrit as Preventive Service

The carrier may determine that Procrit is covered for individuals who:

1. Are undergoing hip or knee surgery

2. Have an anemia with a hemoglobin between 10 and 13 mg/dL;

3. Are not a candidate for autologous blood transfusion;

4. Are expected to lose more than 2 units of blood; and

5. Have had a workup so that their anemia appears to be that of chronic disease.

The preoperative use of Procrit may be afforded to these individuals when carriers, exercising their discretion, determine that this treatment is reasonable and necessary. In other cases, Procrit is considered a preventive service and therefore not covered.

50.5.3 - Oral Anti-Cancer Drugs

(Rev. 1, 10-01-03)
A3-3112.4.B.5, HO-230.4.B.5

Effective January 1, 1994, Medicare Part B coverage is extended to include oral anti-cancer drugs that are prescribed as anti-cancer chemotherapeutic agents providing they

have the same active ingredients and are used for the same indications as anti-cancer chemotherapeutic agents which would be covered if they were not self-administered and they were furnished incident to a physician's service as drugs and biologicals.

For an oral anti-cancer drug to be covered under Part B, it must:

- Be prescribed by a physician or other practitioner licensed under State law to prescribe such drugs as anti-cancer chemotherapeutic agents;

- Be a drug or biological that has been approved by the Food and Drug Administration (FDA);

- Have the same active ingredients as a non-self-administrable anti-cancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service. The oral anti-cancer drug and the non-self-administrable drug must have the same chemical/generic name as indicated by the FDA's "Approved Drug Products" (Orange Book), "Physician's Desk Reference" (PDR), or an authoritative drug compendium;

- Be used for the same indications, including unlabeled uses, as the non-self-administrable version of the drug; and

- Be reasonable and necessary for the individual patient.

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50.5.4 - Oral Anti-Nausea (Anti-Emetic) Drugs

(Rev. 1, 10-01-03)
PM AB-97-26

Effective January 1, 1998, Medicare also covers self-administered anti-emetics, which are necessary for the administration and absorption of the anti-neoplastic chemotherapeutic agents when a high likelihood of vomiting exists. The anti-emetic drug is covered as a necessary means for administration of the antineoplastic chemotherapeutic agents. Oral drugs prescribed for use with the primary drug, which enhance the anti-neoplastic effect of the primary drug or permit the patient to tolerate the primary anti-neoplastic drug in higher doses for longer periods are not covered. Self-administered anti-emetics to reduce the side effects of nausea and vomiting brought on by the primary drug are not included beyond the administration necessary to achieve drug absorption.

Section 1861(s)(2) of the Act extends coverage to oral anti-emetic drugs that are used as full replacement for intravenous dosage forms of a cancer regimen under the following conditions:

- Coverage is provided only for oral drugs approved by the Food and Drug Administration (FDA) for use as anti-emetics;

- The oral anti-emetic must either be administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen;

- Oral anti-emetic drugs administered with a particular chemotherapy treatment must be initiated within two hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time;

- The oral anti-emetic drugs provided must be used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment.

Only drugs pursuant to a physician's order at the time of the chemotherapy treatment qualify for this benefit. The dispensed number of dosage units may not exceed a loading dose administered within two hours of the treatment, plus a supply of additional dosage units not to exceed 48 hours of therapy.

Oral drugs that are not approved by the FDA for use as anti-emetics and which are used by treating physicians adjunctively in a manner incidental to cancer chemotherapy are not covered by this benefit and are not reimbursable within the scope of this benefit.

It is recognized that a limited number of patients will fail on oral anti-emetic drugs. Intravenous anti-emetics may be covered (subject to the rules of medical necessity) when furnished to patients who fail on oral anti-emetic therapy.

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More than one oral anti emetic drug may be prescribed and may be covered for concurrent use if needed to fully replace the intravenous drugs that otherwise would be given.

50.5.5 - Hemophilia Clotting Factors

(Rev. 1, 10-01-03)
A3-3112.4.B.2, HO-230.4.B.2

Section 1861(s)(2)(I) of the Act provides Medicare coverage of blood clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors. Hemophilia, a blood disorder characterized by prolonged coagulation time, is caused by deficiency of a factor in plasma necessary for blood to clot. For purposes of Medicare Part B coverage, hemophilia encompasses the following conditions:

- Factor VIII deficiency (classic hemophilia);

- Factor IX deficiency (also termed plasma thromboplastin component (PTC) or Christmas factor deficiency); and

- Von Willebrand's disease.

Claims for blood clotting factors for hemophilia patients with these diagnoses may be covered if the patient is competent to use such factors without medical supervision.

The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision is based on the historical utilization pattern or profile developed by the contractor for each patient. It is expected that the treating source, e.g., a family physician or comprehensive hemophilia diagnostic and treatment center, have such information. From this data, the contractor is able to anticipate and make reasonable projections concerning the quantity of clotting factors the patient will need over a specific period of time. Unanticipated occurrences involving extraordinary events, such as automobile accidents or inpatient hospital stays, will change this base line data and should be appropriately considered. In addition, changes in a patient's medical needs over a period of time require adjustments in the profile.

50.6 – Coverage of Intravenous Immune Globulin for Treatment of Primary Immune Deficiency Diseases in the Home

(Rev. 6, 01-23-04)

Beginning for dates of service on or after January 1, 2004, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provides coverage of intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases (ICD-9 diagnosis codes 279.04, 279.05, 279.06, 279.12, and 279.2[illegible]) in the home. The corresponding HCPCS codes are J1563 and J1564. The Act defines "intravenous immune globulin" as an approved pooled plasma derivative for the treatment of primary immune deficiency disease. It is covered under this benefit when the patient has a diagnosed primary immune deficiency disease, it is administered in the home of a patient with a diagnosed primary immune deficiency disease, and the physician determines that administration of the derivative in the patient's home is medically appropriate. The benefit does not include coverage for items or services related to the administration of the derivative. For coverage of IVIG under this benefit, it is not necessary for the derivative to be administered through a piece of durable medical equipment.

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60 - Services and Supplies Furnished Incident To a Physician's/NPP's Professional Service

(Rev. 1, 10-01-03)
B3-2050

A - Noninstitutional Setting

For purposes of this section a noninstitutional setting means all settings other than a hospital or skilled nursing facility

Medicare pays for services and supplies (including drug and biologicals which are not usually self-administered) that are furnished incident to a physician's or other practitioner's services, are commonly included in the physician's or practitioner's bills,

and for which payment is not made under a separate benefit category listed in §1861(s) of the Act. Carriers and intermediaries must not apply incident to requirements to services having their own benefit category. Rather, these services should meet the requirements of their own benefit category. For example, diagnostic tests are covered under §1861(s)(3) of the Act and are subject to their own coverage requirements. Depending on the particular tests, the supervision requirement for diagnostic tests or other services may be more or less stringent than supervision requirements for services and supplies furnished incident to physician's or other practitioner's services. Diagnostic tests need not also meet the incident to requirement in this section. Likewise, pneumococcal, influenza, and hepatitis B vaccines are covered under §1861(s)(10) of the Act and need not also meet incident to requirements. (Physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, physical therapists and occupational therapists all have their own benefit categories and may provide services without direct physician supervision and bill directly for these services. When their services are provided as auxiliary personnel (see under direct physician supervision, they may be covered as incident to services, in which case the incident to requirements would apply.

For purposes of this section, physician means physician or other practitioner (physician, physician assistant, nurse practitioner, clinical nurse specialist, nurse midwife, and clinical psychologist) authorized by the Act to receive payment for services incident to his or her own services.

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To be covered incident to the services of a physician or other practitioner, services and supplies must be:

- An integral, although incidental, part of the physician's professional service (see §60.1);
- Commonly rendered without charge or included in the physician's bill (see §60.1A);
- Of a type that are commonly furnished in physician's offices or clinics (see §60.1A);
- Furnished by the physician or by auxiliary personnel under the physician's direct supervision (see §60.1B).

B - Institutional Setting

Hospital services incident to physician's or other practitioner's services rendered to outpatients (including drugs and biologicals which are not usually self-administered by the patient), and partial hospitalization services incident to such services may also be covered.

The hospital's intermediary makes payment for these services under Part B to a hospital.

60.1 - Incident To Physician's Professional Services
(Rev. 1, 10-01-03)
B3-2050.1

Incident to a physician's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's personal professional services in the course of diagnosis or treatment of an injury or illness.

A - Commonly Furnished in Physicians' Offices

Services and supplies commonly furnished in physicians' offices are covered under the incident to provision. Where supplies are clearly of a type a physician is not expected to have on hand in his/her office or where services are of a type not considered medically appropriate to provide in the office setting, they would not be covered under the incident to provision.

Supplies usually furnished by the physician in the course of performing his/her services, e.g., gauze, ointments, bandages, and oxygen, are also covered. Charges for such services and supplies must be included in the physicians' bills. (See §50 regarding coverage of drugs and biologicals under this provision.) To be covered, supplies, including drugs and biologicals, must represent an expense to the physician or legal entity billing fir he services or supplies. For example, where a patient purchases a drug and the physician administers it, the cost of the drug is not covered. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it.

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B - Direct Personal Supervision

Coverage of services and supplies incident to the professional services of a physician in private practice is limited to situations in which there is direct physician supervision of auxiliary personnel.

Auxiliary personnel means any individual who is acting under the supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician, or of the legal entity that employs or contracts with the physician. Likewise, the supervising physician may be an employee, leased employee or independent contractor of the legal entity billing and receiving payment for the services or supplies.

However, the physician personally furnishing the services or supplies or supervising the auxiliary personnel furnishing the services or supplies must have a relationship with the legal entity billing and receiving payment for the services or supplies that satisfies the requirements for valid reassignment. As with the physician's personal professional services, the patient's financial liability for the incident to services or supplies is to the

physician or other legal entity billing and receiving payment for the services or supplies. Therefore, the incident to services or supplies must represent an expense incurred by the physician or legal entity billing for the services or supplies.

Thus, where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician.

This does not mean, however, that to be considered incident to, each occasion of service by auxiliary personnel (or the furnishing of a supply) need also always be the occasion of the actual rendition of a personal professional service by the physician. Such a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment. (However, the direct supervision requirement must still be met with respect to every nonphysician service.)

Direct supervision in the office setting does not mean that the physician must be present in the same room with his or her aide. However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services.

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If auxiliary personnel perform services outside the office setting, e.g., in a patient's home or in an institution (other than hospital or SNF), their services are covered incident to a physician's service only if there is direct supervision by the physician. For example, if a nurse accompanied the physician on house calls and administered an injection, the nurse's services are covered. If the same nurse made the calls alone and administered the injection, the services are not covered (even when billed by the physician) since the physician is not providing direct supervision. Services provided by auxiliary personnel in an institution (e.g., nursing, or convalescent home) present a special problem in determining whether direct physician supervision exists. The availability of the physician by telephone and the presence of the physician somewhere in the institution does not constitute direct supervision. (See §70.3 of the Medicare National Coverage Determinations Manual for instructions used if a physician maintains an office in an institution.) For hospital patients and for SNF patients who are in a Medicare covered stay, there is no Medicare Part B coverage of the services of physician-employed auxiliary personnel as services incident to physicians' services under §1861(s)(2)(A) of the Act. Such services can be covered only under the hospital or SNF benefit and payment for such services can be made to only the hospital or SNF by a Medicare intermediary. (See §80 concerning physician supervision of technicians performing diagnostic x-ray procedures in a physician's office.)

60.2 - Services of Nonphysician Personnel Furnished Incident To Physician's Services

(Rev. 1, 10-01-03)
B3-2050.2

In addition to coverage being available for the services of such auxiliary personnel as nurses, technicians, and therapists when furnished incident to the professional services of a physician (as discussed in §60.1), a physician may also have the services of certain nonphysician practitioners covered as services incident to a physician's professional services. These nonphysician practitioners, who are being licensed by the States under various programs to assist or act in the place of the physician, include, for example, certified nurse midwives, clinical psychologists, clinical social workers, physician assistants, nurse practitioners, and clinical nurse specialists. (See §§150 through 200 for coverage instructions for various allied health/nonphysician practitioners' services.)

Services performed by these nonphysician practitioners incident to a physician's professional services include not only services ordinarily rendered by a physician's office staff person (e.g., medical services such as taking blood pressures and temperatures, giving injections, and changing dressings) but also services ordinarily performed by the physician such as minor surgery, setting casts or simple fractures, reading x-rays, and other activities that involve evaluation or treatment of a patient's condition.

Nonetheless, in order for services of a nonphysician practitioner to be covered as incident to the services of a physician, the services must meet all of the requirements for coverage specified in §§60 through 60.1. For example, the services must be an integral, although incidental, part of the physician's personal professional services, and they must be performed under the physician's direct supervision.

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A nonphysician practitioner such as a physician assistant or a nurse practitioner may be licensed under State law to perform a specific medical procedure and may be able (see §§190 or 200, respectively) to perform the procedure without physician supervision and have the service separately covered and paid for by Medicare as a physician assistant's or nurse practitioner's service. However, in order to have that same service covered as incident to the services of a physician, it must be performed under the direct supervision of the physician as an integral part of the physician's personal in-office service. As explained in §60.1, this does not mean that each occasion of an incidental service performed by a nonphysician practitioner must always be the occasion of a service actually rendered by the physician. It does mean that there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part, and there must be subsequent services by the physician of a frequency that reflects the physician's continuing active participation in and management of the course of treatment. In addition, the physician must be physically present in the same office suite and be immediately available to render assistance if that becomes necessary.

Note also that a physician might render a physician's service that can be covered even though another service furnished by a nonphysician practitioner as incident to the physician's service might not be covered. For example, an office visit during which the

physician diagnoses a medical problem and establishes a course of treatment could be covered even if, during the same visit, a nonphysician practitioner performs a noncovered service such as acupuncture.

60.3 - Incident To Physician's Services in Clinic

(Rev. 1, 10-01-03)
B3-2050.3

Services and supplies incident to a physician's service in a physician directed clinic or group association are generally the same as those described above.

A physician directed clinic is one where:

1. A physician (or a number of physicians) is present to perform medical (rather than administrative) services at all times the clinic is open;

2. Each patient is under the care of a clinic physician; and

3. The nonphysician services are under medical supervision.

In highly organized clinics, particularly those that are departmentalized, direct physician supervision may be the responsibility of several physicians as opposed to an individual attending physician. In this situation, medical management of all services provided in the clinic is assured. The physician ordering a particular service need not be the physician who is supervising the service. Therefore, services performed by auxiliary personnel and other aides are covered even though they are performed in another department of the clinic.

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Supplies provided by the clinic during the course of treatment are also covered. When the auxiliary personnel perform services outside the clinic premises, the services are covered only if performed under the direct supervision of a clinic physician. If the clinic refers a patient for auxiliary services performed by personnel who are not supervised by clinic physicians, such services are not incident to a physician's service.

60.4 - Services Incident to a Physician's Service to Homebound Patients Under General Physician Supervision

(Rev. 1, 10-01-03)
B3-2051

A. When Covered

In some medically underserved areas there are only a few physicians available to provide services over broad geographic areas or to a large patient population. The lack of medical personnel (and, in many instances, a home health agency servicing the area) significantly reduces the availability of certain medical services to homebound patients. Some physicians and physician-directed clinics, therefore, call upon nurses and other

paramedical personnel to provide these services under general (rather than direct) supervision. In some areas, such practice has tended to become the accepted method of delivery of these services.

The Senate Finance Committee Report accompanying the 1972 Amendments to the Act recommended that the direct supervision requirement of the "incident to" provision be modified to provide coverage for services provided in this manner.

Accordingly, to permit coverage of certain of these services, the direct supervision criterion in §60.2 above is **not** applicable to individual or intermittent services outlined in this section when they are performed by personnel meeting any pertinent State requirements (e.g., a nurse, technician, or physician extender) and where the criteria listed below also are met:

1 The patient is homebound; i.e., confined to his or her home (see §60.4.1 for the definition of a "homebound" patient and §110.1 (D) for the definition of patient's "place of residence."

2 The service is an integral part of the physician's service to the patient (the patient must be one the physician is treating), and is performed under general physician supervision by employees of the physician or clinic. General supervision means that the physician need not be physically present at the patient's place of residence when the service is performed; however, the service must be performed under his or her overall supervision and control.

The physician orders the service(s) to be performed, and contact is maintained between the nurse or other employee and the physician, e.g., the employee contacts the physician directly if additional instructions are needed, and the physician must retain professional responsibility for the service. All other "incident to" requirements must be met (see §§60-60.4).

3 The services are included in the physician's/clinic's bill, and the physician or clinic has incurred an expense for them (see §60.2).

4 The services of the paramedical are required for the patient's care; that is, they are reasonable and necessary as defined in the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20.

5 When the service can be furnished by an HHA in the local area, it **cannot** be covered when furnished by a physician/clinic to a homebound patient under this provision, except as described in §60.4.C.

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B. Covered Services

Where the requirements in §60.4.A are met, the direct supervision requirement in §60.2 is not applicable to the following services:

1. Injections;

2. Venipuncture;

3. EKGs;

4. Therapeutic exercises;

5. Insertion and sterile irrigation of a catheter;

6. Changing of catheters and collection of catheterized specimen for urinalysis and culture;

7. Dressing changes, e.g., the most common chronic conditions that may need dressing changes are decubitus care and gangrene;

8. Replacement and/or insertion of nasogastric tubes;

9. Removal of fecal impaction, including enemas;

10. Sputum collection for gram stain and culture, and possible acid-fast and/or fungal stain and culture;

11. Paraffin bath therapy for hands and/or feet in rheumatoid arthritis or osteoarthritis;

12. Teaching and training the patient for:

    a. The care of colostomy and ileostomy;

    b. The care of permanent tracheostomy;

    c. Testing urine and care of the feet (diabetic patients only); and

    d. Blood pressure monitoring.

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Teaching and training services (also referred to as educational services) can be covered only where they provide knowledge essential for the chronically ill patient's participation in his or her own treatment and only where they can be reasonably related to such treatment or diagnosis. Educational services that provide more elaborate instruction than is necessary to achieve the required level of patient education are not covered. After essential information has been provided, the patient should be relied upon to obtain additional information on his or her own.

C. Relation to Home Health Benefits

This coverage should not be considered as an alternative to home health benefits where there is a participating home health agency in the area which could provide the needed services on a timely basis. For example, two of the three services initially included under this coverage - injections and venipuncture - are skilled nursing services that could be covered as home health services (EKG is not a covered Home Health Agency (HHA) service) if the patient is eligible for home health benefits and there is a home health agency available. Thus, postpayment review of these claims will include measures to assure that physicians and clinics do not provide a substantial number of services under this coverage when they could otherwise have been performed by a home health agency.

In these circumstances, the physician or clinic is expected to assist the patient in obtaining such skilled services together with the other home health services (such as aide services). However, HHA services are not considered available where the HHA cannot respond on a timely basis or where the physician could not have foreseen that intermittent services would be needed.

Refer to the Medicare Claims Processing Manual, Chapter 10, "Home Health Agency Billing," for a more in depth discussion of home health services.

60.4.1 - Definition of Homebound Patient Under the Medicare Home Health (HH) Benefit

(Rev. 1, 10-01-03)
B3-2051.1

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This definition applies to homebound for purposes of the Medicare home health benefit. An individual does not have to be bedridden to be considered as confined to home. However, the condition of these patients should be such that there exists a normal inability to leave home and, consequently, leaving his or her home would require a considerable and taxing effort. If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration. It is expected that in most instances absences from the home will be for the purpose of receiving medical treatment. However, occasional absences from the home for nonmedical purposes, e.g., an occasional trip to the barber, a walk around the block, a drive attendance at a family reunion, funeral, graduation, or other infrequent or unique event would not necessitate a finding that the individual is not homebound if absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the health care provided outside rather than in the home.

The above examples are not all-inclusive and are meant to be illustrative of the kinds of infrequent or unique events a patient may attend. Generally speaking, a beneficiary will be considered to be homebound if the beneficiary has a condition due to an illness or injury which restricts ability to leave the residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers, the use of special transportation, or the assistance of another person or if the beneficiary has a condition

which is such that leaving home is medically contraindicated. The following are some examples of homebound patients:

- A beneficiary paralyzed from a stroke who is confined to a wheelchair or who requires the aid of crutches in order to walk;

- A beneficiary who is blind or senile and, therefore, requires the assistance of another person in leaving his or her residence;

- A beneficiary who has lost the use of the upper extremities and, therefore, is unable to open doors, use handrails on stairways, etc., and therefore, requires the assistance of another individual in leaving his or her place of residence;

- A beneficiary who has just returned from a hospital stay involving surgery who may be suffering from resultant weakness and pain and, therefore, his or her actions may be restricted by the physician to certain specified and limited activities such as getting out of bed only for a specified period of time, or walking stairs only once a day;

- A beneficiary with arteriosclerotic heart disease of such severity that the beneficiary must avoid all stress and physical activity;

- A beneficiary with a psychiatric problem if the illness is manifested in part by a refusal to leave the home environment or it is not considered safe for the beneficiary to leave home unattended, even if he/she had no physical limitations, and

- A beneficiary in the late stages of ALS or a neurodegenerative disability.

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In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay. For example, a patient may leave the home (under the conditions described above, e.g., with severe and taxing effort, with the assistance of others) more frequently during a short period when, for example, the presence of visiting relatives provides a unique opportunity for such absences, than is normally the case. So long as the patient's overall condition and experience is such that he or she meets these qualifications, he or she should be considered confined to the home.

The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age is not considered confined to home for purposes of this reimbursement unless the person's condition is analogous to those above.

If for any reason a question is raised as to whether an individual is confined to home, the carrier will ask the physician to furnish the information necessary to establish if the beneficiary is homebound, as defined above.

70 - Sleep Disorder Clinics

(Rev. 1, 10-01-03)
B3-2055

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, which 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.

A. Criteria for Coverage of Diagnostic Tests

All reasonable and necessary diagnostic tests given for the medical conditions listed in subsection B are covered when the following criteria are met:

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- The clinic is either affiliated with a hospital or is under the direction and control of physicians. Diagnostic testing routinely performed in sleep disorder clinics may be covered even in the absence of direct supervision by a physician;

- Patients are referred to the sleep disorder clinic by their attending physicians, and the clinic maintains a record of the attending physician's orders; and

- The need for diagnostic testing is confirmed by medical evidence, e.g., physician examinations and laboratory tests.

Diagnostic testing that is duplicative of previous testing done by the attending physician to the extent the results are still pertinent is not covered because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

B. Medical Conditions for Which Testing is Covered

Diagnostic testing is covered only if the patient has the symptoms or complaints of one of the conditions listed below. Most of the patients who undergo the diagnostic testing are not considered inpatients, although they may come to the facility in the evening for testing and then leave after testing is over. The overnight stay is considered an integral part of these tests.

1. Narcolepsy - This term refers to a syndrome that is characterized by abnormal sleep tendencies, e.g., excessive daytime sleepiness or disturbed nocturnal sleep. Related diagnostic testing is covered if the patient has inappropriate sleep episodes or attacks

(e.g., while driving, in the middle of a meal, in the middle of a conversation), amnesiac episodes, or continuous disabling drowsiness. The sleep disorder clinic must submit documentation that this condition is severe enough to interfere with the patient's well being and health before Medicare benefits may be provided for diagnostic testing. Ordinarily, a diagnosis of narcolepsy can be confirmed by three sleep naps. If more than three sleep naps are claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional test(s). It will use HCPCS procedure codes 95828 and 95805.

2. Sleep Apnea - This is a potentially lethal condition where the patient stops breathing during sleep. Three types of sleep apnea have been described (central, obstructive, and mixed). The nature of the apnea episodes can be documented by appropriate diagnostic testing. Ordinarily, a single polysomnogram and electroencephalogram (EEG) can diagnose sleep apnea. If more than one such testing session is claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional tests. It will use HCPCS procedure codes 95807, 95810, and 95822.

3. Impotence - Diagnostic nocturnal penile tumescence testing may be covered, under limited circumstances, to determine whether erectile impotence in men is organic or psychogenic. Although impotence is not a sleep disorder, the nature of the testing requires that it be performed during sleep. The tests ordinarily are covered only where necessary to confirm the treatment to be given (surgical, medical, or psychotherapeutic). Ordinarily, a diagnosis may be determined by two nights of diagnostic testing. If more than two nights of testing are claimed, the carrier will require persuasive medical evidence justifying the medical necessity for the additional tests. It will have its medical staff review questionable cases to ensure that the tests are reasonable and necessary for the individual. It will use HCPCS procedure code 54250. (See the Medicare National Coverage Determinations Manual, Chapter 1, for policy on coverage of diagnosis and treatment of impotence.)

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4. Parasomnia - Parasomnias are a group of conditions that represent undesirable or unpleasant occurrences during sleep. Behavior during these times can often lead to damage to the surroundings and injury to the patient or to others. Parasomnia may include conditions such as sleepwalking, sleep terrors, and rapid eye movement (REM) sleep behavior disorders. In many of these cases, the nature of these conditions may be established by careful clinical evaluation. Suspected seizure disorders as possible cause of the parasomnia are appropriately evaluated by standard or prolonged sleep EEG studies. In cases where seizure disorders have been ruled out and in cases that present a history of repeated violent or injurious episodes during sleep, polysomnography may be useful in providing a diagnostic classification or prognosis. The carrier must use HCPCS procedure codes 95807, 95810, and/or 95822.

C. Polysomnography for Chronic Insomnia Is Not Covered.

Evidence at the present time is not convincing that polysomnography in a sleep disorder clinic for chronic insomnia provides definitive diagnostic data or that such information is useful in patient treatment or is associated with improved clinical outcome. The use of polysomnography for diagnosis of patients with chronic insomnia is not covered under Medicare because it is not reasonable and necessary under §1862(a)(1)(A) of the Act.

D. Coverage of Therapeutic Services.
Sleep disorder clinics may at times render therapeutic as well as diagnostic services. Therapeutic services may be covered in a hospital outpatient setting or in a freestanding facility provided they meet the pertinent requirements for the particular type of services and are reasonable and necessary for the patient, and are performed under the direct supervision of a physician.

80 - Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests

(Rev. 116, Issued: 12-11-09, Effective: 01-01-10, Implementation: 01-04-10)

This section describes the levels of physician supervision required for furnishing the technical component of diagnostic tests for a Medicare beneficiary who is not a hospital inpatient. For hospital outpatient diagnostic services, the supervision levels assigned to each CPT or Level II HCPCS code in the Medicare Physician Fee Schedule Relative Value File that is updated quarterly, apply as described below. For more information, see Chapter 6 (Hospital Services Covered Under Part B), §20.4 (Outpatient Diagnostic Services).

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Section 410.32(b) of the Code of Federal Regulations (CFR) requires that diagnostic tests covered under §1861(s)(3) of the Act and payable under the physician fee schedule, with certain exceptions listed in the regulation, have to be performed under the supervision of an individual meeting the definition of a physician (§1861(r) of the Act) to be considered reasonable and necessary and, therefore, covered under Medicare. The regulation defines these levels of physician supervision for diagnostic tests as follows:

General Supervision - means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

Direct Supervision - in the office setting means the physician must be present in the office suite 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.

Personal Supervision - means a physician must be in attendance in the room during the performance of the procedure.

One of the following numerical levels is assigned to each CPT or HCPCS code in the Medicare Physician Fee Schedule Database:

0 Procedure is not a diagnostic test or procedure is a diagnostic test which is not subject to the physician supervision policy.

1 Procedure must be performed under the general supervision of a physician.

2 Procedure must be performed under the direct supervision of a physician.

3 Procedure must be performed under the personal supervision of a physician.

4 Physician supervision policy does not apply when procedure is furnished by a qualified, independent psychologist or a clinical psychologist or furnished under the general supervision of a clinical psychologist; otherwise must be performed under the general supervision of a physician.

5 Physician supervision policy does not apply when procedure is furnished by a qualified audiologist; otherwise must be performed under the general supervision of a physician.

6 Procedure must be performed by a physician or by a physical therapist (PT) who is certified by the American Board of Physical Therapy Specialties (ABPTS) as a qualified electrophysiologic clinical specialist and is permitted to provide the procedure under State law.

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6a Supervision standards for level 66 apply; in addition, the PT with ABPTS certification may supervise another PT but only the PT with ABPTS certification may bill.

7a Supervision standards for level 77 apply; in addition, the PT with ABPTS certification may supervise another PT but only the PT with ABPTS certification may bill.

9 Concept does not apply.

21 Procedure must be performed by a technician with certification under general supervision of a physician; otherwise must be performed under direct supervision of a physician.

22 Procedure may be performed by a technician with on-line real-time contact with physician.

66 Procedure must be performed by a physician or by a PT with ABPTS certification and certification in this specific procedure.

77 Procedure must be performed by a PT with ABPTS certification or by a PT without certification under direct supervision of a physician, or by a technician with certification under general supervision of a physician.

Nurse practitioners, clinical nurse specialists, and physician assistants are not defined as physicians under §1861(r) of the Act. Therefore, they may not function as supervisory physicians under the diagnostic tests benefit (§1861(s)(3) of the Act). However, when these practitioners personally perform diagnostic tests as provided under §1861(s)(2)(K) of the Act, §1861(s)(3) does not apply and they may perform diagnostic tests pursuant to State scope of practice laws and under the applicable State requirements for physician supervision or collaboration.

Because the diagnostic tests benefit set forth in §1861(s)(3) of the Act is separate and distinct from the incident to benefit set forth in §1861(s)(2) of the Act, diagnostic tests need not meet the incident to requirements. Diagnostic tests may be furnished under situations that meet the incident to requirements but this is not required. However, carriers must not scrutinize claims for diagnostic tests utilizing the incident to requirements.

80.1 - Clinical Laboratory Services

(Rev. 79; Issued: 10-19-07; Effective: 01-01-03; Implementation: 11-19-07)

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Section 1833 and 1861 of the Act provides for payment of clinical laboratory services under Medicare Part B. Clinical laboratory services involve the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the diagnosis, prevention, or treatment of a disease or assessment of a medical condition. Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in 42 CFR 410.32(a)(3).

See section 80.6 of this manual for related physician ordering instructions.

See the Medicare Claims Processing Manual Chapter 16 for related claims processing instructions.

80.1.1 - Certification Changes

(Rev. 1, 10-01-03)
B3-2070.1.E

Each page of the lists of approved specialties also includes a column “Certification Changed” in which the following codes are used:

"C" indicates a change in the laboratory's approved certification since the preceding listing.

"A" discloses an accretion.

"TERM" - Laboratory not approved for payment after the indicated date which follows the code. The reason for termination also is given in the following codes:

1. Involuntary termination - no longer meets requirements
2. Voluntary withdrawal
3. Laboratory closed, merged with other interests, or organizational change
4. Ownership change with new ownership participating under different name
5. Ownership change with new owner not participating
6. Change in ownership - new provider number assigned
7. Involuntary termination - failure to abide by agreement
8. Former "emergency" hospital now fully participating

80.1.2 - Carrier Contacts With Independent Clinical Laboratories

(Rev. 1, 10-01-03)
B3-2070.1.F

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An important role of the carrier is as a communicant of necessary information to independent clinical laboratories. Experience has shown that the failure to inform laboratories of Medicare regulations and claims processing procedures may have an adverse effect on prosecution of laboratories suspected of fraudulent activities with respect to tests performed by, or billed on behalf of, independent laboratories. United States Attorneys often have to prosecute under a handicap or may simply refuse to prosecute cases where there is no evidence that a laboratory has been specifically informed of Medicare regulations and claims processing procedures.

Carriers must follow the Provider Education and Training (PET) guidelines to assure that laboratories are aware of Medicare regulations and the carrier's policy when any changes are made in coverage policy or claims processing procedures. The PET guidelines require carriers to use various methods of communication (such as print, Internet, face-to-face instruction). Newsletters/bulletins that contain program and billing information must be produced at least quarterly and posted on the carrier Web site where duplicate copies may be obtained.

Some items which should be communicated to laboratories and responsibilities that laboratories are required to perform are:

- The requirements to have the same fee schedule for Medicare and private patients;
- To specify whether the tests are manual or automated;

- To document fully the medical necessity for pickup of specimens from a skilled nursing facility or a beneficiary's home, and

- In cases when a laboratory service is referred from one independent laboratory to another independent laboratory, to identify the laboratory actually performing the test.

Additionally, when carrier professional relations representatives make personal contacts with particular laboratories, the representative should prepare and retain reports of contact indicating dates, persons present, and issues discussed. Finally, carriers should inform independent laboratories that the Medicare National Coverage Determinations Manual as well as other guidelines contained in the manual for determining medical necessity are on the Web site. Carriers should also publish local guidelines on its Web site; the carrier should not duplicate national instructions here. Timely paper or electronic communications concerning the Internet publications to independent laboratories new to the carrier's service area are essential.

80.1.3 - Independent Laboratory Service to a Patient in the Patient's Home or an Institution

(Rev. 1, 10-01-03)
B3-2070.1.G

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Where it is medically necessary for an independent laboratory to visit a patient to obtain a specimen, the service would be covered in the following circumstances:

1. Patient Confined to Home

If a patient is confined to the home or other place of residence used as his or her home (see §60.4.1 for the definition of a "homebound patient"), medical necessity would exist (e.g., where a laboratory technician draws a blood specimen). However, where the specimen is a type which would require only the services of a messenger and would not require the skills of a laboratory technician, e.g., urine or sputum, a specimen pickup service would not be considered medically necessary.

2. Place of Residence is an Institution

Medical necessity could also exist where the patient's place of residence is an institution, including a skilled nursing facility that does not perform venipunctures. This would apply even though the institution meets the basic definition of a skilled nursing facility and would not ordinarily be considered a beneficiary's home. (This policy is intended for independent laboratories only and does not expand the range of coverage of services to homebound patients under the incident to provision.) A trip by an independent laboratory technician to a facility (other than a hospital) for the purpose of performing a venipuncture is considered medically necessary only if:

a. The patient was confined to the facility; and

b. The facility did not have on duty personnel qualified to perform this service.

When facility personnel actually obtained and prepared the specimens for the independent laboratory to pick them up, the laboratory provides this pickup service as a service to the facility in the same manner as it does for physicians.

80.2 - Psychological Tests and Neuropsychological Tests

(Rev. 85, Issued: 02-29-08, Effective: 01-01-06, Implementation: 12-28-06)

Medicare Part B coverage of psychological tests and neuropsychological tests is authorized under section 1861(s)(3) of the Social Security Act. Payment for psychological and neuropsychological tests is authorized under section 1842(b)(2)(A) of the Social Security Act. The payment amounts for the new psychological and neuropsychological tests (CPT codes 96102, 96103, 96119 and 96120) that are effective January 1, 2006, and are billed for tests administered by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings. Additionally, there is no authorization for payment for diagnostic tests when performed on an "incident to" basis.

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Under the diagnostic tests provision, all diagnostic tests are assigned a certain level of supervision. Generally, regulations governing the diagnostic tests provision require that only physicians can provide the assigned level of supervision for diagnostic tests. However, there is a regulatory exception to the supervision requirement for diagnostic psychological and neuropsychological tests in terms of who can provide the supervision. That is, regulations allow a clinical psychologist (CP) or a physician to perform the general supervision assigned to diagnostic psychological and neuropsychological tests.

In addition, nonphysician practitioners such as nurse practitioners (NPs), clinical nurse specialists (CNSs) and physician assistants (PAs) who personally perform diagnostic psychological and neuropsychological tests are excluded from having to perform these tests under the general supervision of a physician or a CP. Rather, NPs and CNSs must perform such tests under the requirements of their respective benefit instead of the requirements for diagnostic psychological and neuropsychological tests. Accordingly, NPs and CNSs must perform tests in collaboration (as defined under Medicare law at section 1861(aa)(6) of the Act) with a physician. PAs perform tests under the general supervision of a physician as required for services furnished under the PA benefit.

Furthermore, physical therapists (PTs), occupational therapists (OTs) and speech language pathologists (SLPs) are authorized to bill three test codes as "sometimes therapy" codes. Specifically, CPT codes 96105, 96110 and 96111 may be performed by these therapists. However, when PTs, OTs and SLPs perform these three tests, they must be performed under the general supervision of a physician or a CP.

<u>Who May Bill for Diagnostic Psychological and Neuropsychological Tests</u>

- CPs – see qualifications under chapter 15, section 160 of the Benefits Policy Manual, Pub. 100-02.

- NPs –to the extent authorized under State scope of practice. See qualifications under chapter 15, section 200 of the Benefits Policy Manual, Pub. 100-02.

- CNSs –to the extent authorized under State scope of practice. See qualifications under chapter 15, section 210 of the Benefits Policy Manual, Pub. 100-02.

- PAs – to the extent authorized under State scope of practice. See qualifications under chapter 15, section 190 of the Benefits Policy Manual, Pub. 100-02.

- Independently Practicing Psychologists (IPPs)

- PTs, OTs and SLPs – see qualifications under chapter 15, sections 220-230.6 of the Benefits Policy Manual, Pub. 100-02.

Psychological and neuropsychological tests performed by a psychologist (who is not a CP) practicing independently of an institution, agency, or physician's office are covered when a physician orders such tests. An IPP is any psychologist who is licensed or certified to practice psychology in the State or jurisdiction where furnishing services or, if the jurisdiction does not issue licenses, if provided by any practicing psychologist. (It is CMS' understanding that all States, the District of Columbia, and Puerto Rico license psychologists, but that some trust territories do not. Examples of psychologists, other than CPs, whose psychological and neuropsychological tests are covered under the diagnostic tests provision include, but are not limited to, educational psychologists and counseling psychologists.)

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The carrier must secure from the appropriate State agency a current listing of psychologists holding the required credentials to determine whether the tests of a particular IPP are covered under Part B in States that have statutory licensure or certification. In States or territories that lack statutory licensing or certification, the carrier checks individual qualifications before provider numbers are issued. Possible reference sources are the national directory of membership of the American Psychological Association, which provides data about the educational background of individuals and indicates which members are board-certified, the records and directories of the State or territorial psychological association, and the National Register of Health Service Providers. If qualification is dependent on a doctoral degree from a currently accredited program, the carrier verifies the date of accreditation of the school involved, since such accreditation is not retroactive. If the listed reference sources do not provide enough information (e.g., the psychologist is not a member of one of these sources), the carrier contacts the psychologist personally for the required information. Generally, carriers maintain a continuing list of psychologists whose qualifications have been verified.

NOTE: When diagnostic psychological tests are performed by a psychologist who is not practicing independently, but is on the staff of an institution, agency, or clinic, that entity bills for the psychological tests.

The carrier considers psychologists as practicing independently when:

- They render services on their own responsibility, free of the administrative and professional control of an employer such as a physician, institution or agency;
- The persons they treat are their own patients; and
- They have the right to bill directly, collect and retain the fee for their services.

A psychologist practicing in an office located in an institution may be considered an independently practicing psychologist when both of the following conditions exist:

- The office is confined to a separately-identified part of the facility which is used solely as the psychologist's office and cannot be construed as extending throughout the entire institution; and
- The psychologist conducts a private practice, i.e., services are rendered to patients from outside the institution as well as to institutional patients.

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Payment for Diagnostic Psychological and Neuropsychological Tests

Expenses for diagnostic psychological and neuropsychological tests are not subject to the outpatient mental health treatment limitation, that is, the payment limitation on treatment services for mental, psychoneurotic and personality disorders as authorized under Section 1833(c) of the Act. The payment amount for the new psychological and neuropsychological tests (CPT codes 96102, 96103, 96119 and 96120) that are billed for tests performed by a technician or a computer reflect a site of service payment differential for the facility and non-facility settings. CPs, NPs, CNSs and PAs are required by law to accept assigned payment for psychological and neuropsychological tests. However, while IPPs are not required by law to accept assigned payment for these tests, they must report the name and address of the physician who ordered the test on the claim form when billing for tests.

CPT Codes for Diagnostic Psychological and Neuropsychological Tests

The range of CPT codes used to report psychological and neuropsychological tests is 96101-96120. CPT codes 96101, 96102, 96103, 96105, 96110, and 96111 are appropriate for use when billing for psychological tests. CPT codes 96116, 96118, 96119 and 96120 are appropriate for use when billing for neuropsychological tests.

All of the tests under this CPT code range 96101-96120 are indicated as active codes under the physician fee schedule database and are covered if medically necessary.

Payment and Billing Guidelines for Psychological and Neuropsychological Tests

The technician and computer CPT codes for psychological and neuropsychological tests include practice expense, malpractice expense and professional work relative value units. Accordingly, CPT psychological test code 96101 should not be paid when billed for the same tests or services performed under psychological test codes 96102 or 96103. CPT neuropsychological test code 96118 should not be paid when billed for the same tests or services performed under neuropsychological test codes 96119 or 96120. However, CPT codes 96101 and 96118 can be paid separately on the rare occasion when billed on the same date of service for different and separate tests from 96102, 96103, 96119 and 96120.

Under the physician fee schedule, there is no payment for services performed by students or trainees. Accordingly, Medicare does not pay for services represented by CPT codes 96102 and 96119 when performed by a student or a trainee. However, the presence of a student or a trainee while the test is being administered does not prevent a physician, CP, IPP, NP, CNS or PA from performing and being paid for the psychological test under 96102 or the neuropsychological test under 96119.

80.3 - Audiology Services

(Rev. 132, Issued: 09-03-10, Effective: 09-30-10, Implementation: 09-30-10)

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References.

1861(ll)(3) of the Social Security Act for the definition of audiology services.

1861(ll)(4)(B) of the Social Security Act for qualifications of audiologists.

42 CFR 410.32(b) for the physician supervision requirements for diagnostic tests.

Pub. 100-04, chapter 12, section 30.3 for coding and billing information related to audiological services and aural rehabilitation.

Pub. 100-02, chapter 15, sections 220 and 230 for the physical therapy and speech-language pathology policies relative to aural rehabilitation and balance, section 60 for services incident to a physician's service, and section 80.6 for policies relevant to ordering for diagnostic tests.

Pub. 100-02, chapter 16, section 100 for hearing aid policies.

A list of audiology services is found at: www.cms.gov/therapyservices.

A. Benefit.

Hearing and balance assessment services are generally covered as “other diagnostic tests” under section 1861(s)(3) of the Social Security Act. Hearing and balance assessment services furnished to an outpatient of a hospital are covered as “diagnostic services” under section 1861(s)(2)(C).

As defined in the Social Security Act, section 1861(ll)(3), the term “audiology services” specifically means such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), as would otherwise be covered if furnished by a physician.

Herein after in this section, hearing and balance assessment services are termed “audiology services,” regardless of whether they are furnished by an audiologist, physician, nonphysician practitioner (NPP), or hospital.

Because audiology services are diagnostic tests, when furnished by a physician in an office or hospital outpatient department, they must be furnished under the appropriate level of supervision of a physician as established in 42 CFR 410.32(b)(1) and 410.28(e). However, as specified in 42 CFR 410.32(b)(2)(ii) or (v), respectively, they are excepted from physician supervision when they are personally furnished by a qualified audiologist or performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

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Audiological diagnostic testing refers to tests of the audiological and vestibular systems, e.g., hearing, balance, auditory processing, tinnitus and diagnostic programming of certain prosthetic devices, performed by qualified audiologists.

Audiological diagnostic tests are not covered under the benefit for services incident to a physician’s service (described in Pub. 100-02, chapter 15, section 60), because they have their own benefit as “other diagnostic tests”. See Pub. 100-04, chapter 13 for general diagnostic test policies.

Audiology services, like all other services, should be reported under the most specific HCPCS code that describes the service that was furnished and in accordance with all CPT guidance and Medicare national and local contractor instructions.

B. Orders.

Audiology tests are covered as “other diagnostic tests” under section 1861(s)(3) or 1861(s)(2)(C) of the Act in the physician’s office or hospital outpatient settings, respectively, when a physician (or an NPP, as applicable) orders such testing for the purpose of obtaining information necessary for the physician’s diagnostic medical evaluation or to determine the appropriate medical or surgical treatment of a hearing deficit or related medical problem. See section 80.6 of this chapter for policies regarding the ordering of diagnostic tests.

If a beneficiary undergoes diagnostic testing performed by an audiologist without a physician order, the tests are not covered even if the audiologist discovers a pathologic condition.

When a qualified physician orders a qualified technician (see definition in subsection D of this section) to furnish an appropriate audiology service, that order must specify which test is to be furnished by the technician under the direct supervision of a physician. Only that test may be provided on that order by the technician.

When the qualified physician or NPP orders diagnostic audiology services furnished by an audiologist without naming specific tests, the audiologist may select the appropriate battery of tests.

C. Coverage and Payment for Audiology Services.

Diagnostic services furnished by a qualified audiologist meeting the requirements in section 80.3.1 of this chapter or physicians and NPPs as described in section 80.6 are covered and payable under the MPFS as "other diagnostic tests."

Services furnished in a hospital outpatient department are covered and payable under the hospital Outpatient Prospective Payment System (OPPS) or other payment methodology applicable to the provider furnishing the services.

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Coverage and, therefore, payment for audiological diagnostic tests is determined by the reason the tests were performed, rather than by the diagnosis or the patient's condition.

Under any Medicare payment system, payment for audiological diagnostic tests is not allowed by virtue of their exclusion from coverage in section 1862(a)(7) of the Social Security Act when:

- The type and severity of the current hearing, tinnitus or balance status needed to determine the appropriate medical or surgical treatment is known to the physician before the test; or

- The test was ordered for the specific purpose of fitting or modifying a hearing aid.

Payment of audiological diagnostic tests is allowed for other reasons and is not limited, for example, by:

- Any information resulting from the test, for example:

    - Confirmation of a prior diagnosis;
    - Post-evaluation diagnoses; or
    - Treatment provided after diagnosis, including hearing aids, or

- The type of evaluation or treatment the physician anticipates before the diagnostic test; or

- Timing of reevaluation. Reevaluation is appropriate at a schedule dictated by the ordering physician when the information provided by the diagnostic test is required, for example, to determine changes in hearing, to evaluate the appropriate medical or surgical treatment or to evaluate the results of treatment. For example, reevaluation may be appropriate, even when the evaluation was recent, in cases where the hearing loss, balance, or tinnitus may be progressive or fluctuating, the patient or caregiver complains of new symptoms, or treatment (such as medication or surgery) may have changed the patient's audiological condition with or without awareness by the patient.

Examples of appropriate reasons for ordering audiological diagnostic tests that could be covered include, but are not limited to:

- Evaluation of suspected change in hearing, tinnitus, or balance;

- Evaluation of the cause of disorders of hearing, tinnitus, or balance;

- Determination of the effect of medication, surgery, or other treatment;

- Reevaluation to follow-up changes in hearing, tinnitus, or balance that may be caused by established diagnoses that place the patient at probable risk for a change in status including, but not limited to: otosclerosis, atelectatic tympanic membrane, tympanosclerosis, cholesteatoma, resolving middle ear infection, Meniére's disease, sudden idiopathic sensorineural hearing loss, autoimmune inner ear disease, acoustic neuroma, demyelinating diseases, ototoxicity secondary to medications, or genetic vascular and viral conditions;

- Failure of a screening test (although the screening test is not covered);

- Diagnostic analysis of cochlear or brainstem implant and programming; and

- Audiology diagnostic tests before and periodically after implantation of auditory prosthetic devices.

If a physician refers a beneficiary to an audiologist for testing related to signs or symptoms associated with hearing loss, balance disorder, tinnitus, ear disease, or ear injury, the audiologist's diagnostic testing services should be covered even if the only outcome is the prescription of a hearing aid.

<u>D. Individuals Who Furnish Audiology Tests.</u>

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1. Qualified Professionals. See section 80.3.1 of this chapter for the qualifications of audiologists. See section 80.6 of this chapter for the qualifications of physicians and NPPs who may furnish diagnostic tests.

2. Qualified Technicians or Other Qualified Staff. References to technicians in this section include other qualified clinical staff. The qualifications for technicians vary locally and may also depend on the type of test, the patient, and the level of participation of the physician who is directly supervising the test. Therefore, an individual must meet qualifications appropriate to the service furnished as determined by the contractor to whom the claim is billed. If it is necessary to determine whether the individual who furnished the labor for appropriate audiology services is qualified, contractors may request verification of any relevant education and training that has been completed by the technician, which shall be available in the records of the clinic or facility.

Depending on the qualifications determined by the contractor, individuals who are also hearing instrument specialists, students of audiology, or other health care professionals may furnish the labor for appropriate audiology services under direct physician supervision when these services are billed by physicians or hospital outpatient departments.

E. Documentation for Audiology Services.

1. Documentation for Orders (Reasons for Tests).

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The reason for the test should be documented either on the order, on the audiological evaluation report, or in the patient's medical record. (See subsection C. of this section concerning reasons for tests.)

2. Documenting skilled services. When the medical record is subject to medical review, it is necessary that the record contains sufficient information so that the contractor may determine that the service qualifies for payment. For example, documentation should indicate that the test was ordered, that the reason for the test results in coverage, and that the test was furnished to the patient by a qualified individual.

Records that support the appropriate provision of an audiological diagnostic test shall be made available to the contractor on request.

F. Audiological Treatment.

There is no provision in the law for Medicare to pay audiologists for therapeutic services. For example, vestibular treatment, auditory rehabilitation treatment, auditory processing treatment, and canalith repositioning, while they are generally within the scope of practice of audiologists, are not those hearing and balance assessment services that are defined as audiology services in 1861(ll)(3) of the Social Security Act and, therefore, shall not be billed by audiologists to Medicare. Services for the purpose of hearing aid evaluation and fitting are not covered regardless of how they are billed. Services

identified as “always” therapy in Pub. 100-04, chapter 5, section 20 may not be billed by hospitals, physicians, NPPs, or audiologists when provided by audiologists. (See also Pub. 100-04, chapter 12, section 30.3.)

Treatment related to hearing may be covered under the speech-language pathology benefit when the services are provided by speech-language pathologists. Treatment related to balance (e.g., services described by “always therapy” codes 97001-97004, 97110, 97112, 97116, and 97750) may be covered under the physical therapy or occupational therapy benefit when the services are provided by therapists or their assistants, where appropriate. Covered therapy services incident to a physician’s service must conform to policies in sections 60, 220, and 230 of this chapter. Audiological treatment provided under the benefits for physical therapy and speech-language pathology services may also be personally provided and billed by physicians and NPPs when the services are within their scope of practice and consistent with State and local laws.

For example, aural rehabilitation and signed communication training may be payable according to the benefit for speech-language pathology services or as speech-language pathology services incident to a physician’s or NPP’s service. Treatment for balance disorders may be payable according to the benefit for physical therapy services or as a physical therapy service incident to the services of a physician or NPP. See the policies in this chapter, sections 220 and 230, for details.

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G. Assignment.

Nonhospital entities billing for the audiologist’s services may accept assignment under the usual procedure or, if not accepting assignment, may charge the patient and submit a nonassigned claim on their behalf.

H. Opt Out and Mandatory Claims Submissions.

The opt out law does not define “physician” or “practitioner” to include audiologists; therefore, they may not opt out of Medicare and provide services under private contracts. See section 40.4 of this chapter for details.

When a physician or supplier furnishes a service that is covered by Medicare, then it is subject to the mandatory claim submission provisions of section 1848(g)(4) of the Social Security Act. Therefore, if an audiologist charges or attempts to charge a beneficiary any remuneration for a service that is covered by Medicare, then the audiologist must submit a claim to Medicare.

I. Non-Audiology Services Furnished by Audiologists.

Audiologists may be qualified to furnish all or part of some diagnostic tests or treatments that are not defined as audiology services under the MPFS, such as non-auditory evoked potentials or cerumen removal. Audiologists may not bill Medicare for services that are

not audiology services according to Medicare's definition (see list at: www.cms.gov/therapyservices). However, the labor for the Technical Component (TC) of certain other diagnostic tests or treatment services may qualify to be billed when furnished by audiologists under physician supervision when all the appropriate policies are followed.

When furnishing services that are not on the Medicare list of audiology services, the audiologist may or may not be working within the scope of practice of an audiologist according to State law. The audiologist furnishing the service must have the qualifications that are ordinarily required of any person providing that service. Consult the following policies for details:

- Policies for physical therapy, occupational therapy, and speech-language pathology services are in sections 220 and 230 of this chapter and in Pub. 100-04, chapter 5, sections 10 and 20.

- Policies for services furnished incident to physicians' services in the physician's office are in section 60 of this chapter.

- Policies for therapeutic services furnished incident to physicians' services in the hospital outpatient setting are in chapter 6, section 20.5, of this manual.

- Policies for diagnostic tests in the physician's office are in section 80 of this chapter.

- Policies for diagnostic tests furnished in the hospital outpatient setting are in chapter 6, section 20.4, of this manual.

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Therapeutic or treatment services that are not audiology services and are not "always" therapy (according to the policy in Pub.100-04, chapter 5, section 20) and are furnished by audiologists may be billed incident to the services of a physician when all other appropriate requirements are met.

In addition, the TC or facility services for diagnostic tests that are not audiology services may be billed by physicians or hospital outpatient departments when provided by qualified personnel (who may be audiologists), and physicians and hospital outpatient departments may bill for these diagnostic tests when provided by those qualified personnel under the specified level of physician supervision for the diagnostic test.

80.3.1 - Definition of Qualified Audiologist

(Rev. 84; Issued: 02-29-08; Effective: 04-01-08; Implementation: 04-07-08)

Audiological tests require the skills of an audiologist and shall be furnished by qualified audiologists, or, in States where it is allowed by State and local laws, by a physician or non-physician practitioner. Medicare is not authorized to pay for these services when performed by audiological aides, assistants, technicians, or others who do not meet the

qualifications below. In cases where it is not clear, the Medicare contractor shall determine whether a service is an audiological service that requires the skills of an audiologist and whether the qualifications for an audiologist have been met.

Section 1861(ll)(3) of the Act, provides that a qualified audiologist is an individual with a master's or doctoral degree in audiology. Therefore, a Doctor of Audiology (AuD) 4th year student with a provisional license from a State does not qualify unless he or she also holds a master's or doctoral degree in audiology. In addition, a qualified audiologist is an individual who:

- Is licensed as an audiologist by the State in which the individual furnishes such services, or

- In the case of an individual who furnishes services in a State which does not license audiologists has:

    - Successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), and

    - Performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and

    - Successfully completed a national examination in audiology approved by the Secretary.

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If it is necessary to determine whether a particular audiologist is qualified under the above definition, the carrier should check references. Carriers in States that have statutory licensure or certification should secure from the appropriate State agency a current listing of audiologists holding the required credentials. Additional references for determining an audiologist's professional qualifications are the national directory published annually by the American Speech-Language-Hearing Association and records and directories, which may be available from the State Licensing Authority.

80.4 - Coverage of Portable X-Ray Services Not Under the Direct Supervision of a Physician

(Rev. 1, 10-01-03)
B3-2070.4

80.4.1 - Diagnostic X-Ray Tests

(Rev. 1, 10-01-03)
B3-2070.4.A

Diagnostic x-ray services furnished by a portable x-ray supplier are covered under Part B when furnished in a place or residence used as the patient's home and in nonparticipating

institutions. These services must be performed under the general supervision of a physician, the supplier must meet FDA certification requirements, and certain conditions relating to health and safety (as prescribed by the Secretary) must be met.

Diagnostic portable x-ray services are also covered under Part B when provided in participating SNFs and hospitals, under circumstances in which they cannot be covered under hospital insurance, i.e., the services are not furnished by the participating institution either directly or under arrangements that provide for the institution to bill for the services. (See §250 for Part B services furnished to inpatients of participating and nonparticipating institutions.)

80.4.2 - Applicability of Health and Safety Standards

(Rev. 1, 10-01-03)
B3-2070.4.B

The health and safety standards apply to all suppliers of portable x-ray services, except physicians who provide immediate personal supervision during the administration of diagnostic x-ray services. Payment is made only for services of approved suppliers who have been found to meet the standards. Notice of the coverage dates for services of approved suppliers are given to carriers by the RO.

When the services of a supplier of portable x-ray services no longer meet the conditions of coverage, physicians having an interest in the supplier's certification status must be notified. The notification action regarding suppliers of portable x-ray equipment is the same as required for decertification of independent laboratories, and the procedures explained in §80.1.3 are followed.

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80.4.3 - Scope of Portable X-Ray Benefit

(Rev. 71, Issued: 05-25-07, Effective: N/A; Implementation: July 2, 2007)

In order to avoid payment for services, which are inadequate or hazardous to the patient, the scope of the covered portable x-ray benefit is defined as:

- Skeletal films involving the extremities, pelvis, vertebral column, or skull;
- Chest films which do not involve the use of contrast media (except routine screening procedures and tests in connection with routine physical examinations);
- Abdominal films which do not involve the use of contrast media; and
- Diagnostic mammograms if the approved portable x-ray supplier, as defined in 42 CFR part 486, subpart C, meets the certification requirements of section 354 of the Public Health Services Act, as implemented by 21 CFR part 900, subpart B.

80.4.4 - Exclusions From Coverage as Portable X-Ray Services

(Rev. 1, 10-01-03)

B3-2070.4.D

Procedures and examinations which are not covered under the portable x-ray provision include the following:

- Procedures involving fluoroscopy;
- Procedures involving the use of contrast media;
- Procedures requiring the administration of a substance to the patient or injection of a substance into the patient and/or special manipulation of the patient;
- Procedures which require special medical skill or knowledge possessed by a doctor of medicine or doctor of osteopathy or which require that medical judgment be exercised;
- Procedures requiring special technical competency and/or special equipment or materials;
- Routine screening procedures; and
- Procedures which are not of a diagnostic nature.

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80.4.5 - Electrocardiograms

(Rev. 1, 10-01-03)
B3-2070.4.F

The taking of an electrocardiogram tracing by an approved supplier of portable x-ray services may be covered as an "other diagnostic test." The health and safety standards referred to in §80.4.2 are applicable to such diagnostic EKG services, e.g., the technician must meet the personnel qualification requirements in the conditions for coverage of portable x-ray services.

80.5 - Bone Mass Measurements (BMMs)

(Rev.70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

80.5.1 - Background

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

On June 24, 1998, CMS published an Interim Final Rule with Comment Period (IFC) in the **Federal Register** entitled "Medicare Coverage of and Payment for Bone Mass Measurements." This IFC implemented section 4106 of the Balanced Budget Act of 1997 by establishing conditions for coverage and frequency standards thereby providing uniform coverage under Medicare Part B. It was effective July1, 1998.

On December 1, 2006, CMS published the CY 2007 Physician Fee Schedule final rule. This rule implemented several changes effective January 1, 2007, which are reflected below.

80.5.2 - Authority

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Definitions can be found in sections 1861(s)(15) and (rr)(1) of the Social Security Act (the Act). Conditions for coverage and frequency standards can be found in 42 CFR 410.31. Denials as not reasonable and necessary can be found at §1862(a)(1)(A) of the Act, 42 CFR 410.31(e), and 42 CFR 411.15(k).

80.5.3 - Definition

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

BMM means a radiologic, radioisotopic, or other procedure that meets all of the following conditions:

- Is performed to identify bone mass, detect bone loss, or determine bone quality.
- Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the Food and Drug Administration (FDA) under 21 CFR part 807, or approved for marketing under 21 CFR part 814.
- Includes a physician's interpretation of the results.

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80.5.4 - Conditions for Coverage

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Medicare covers BMM under the following conditions:

1. Is ordered by the physician or qualified nonphysician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used.

   A physician or qualified nonphysician practitioner treating the beneficiary for purposes of this provision is one who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results in the management of the patient. For the purposes of the BMM benefit, qualified nonphysician practitioners include physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives.

2. Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).

3. Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6.

4. In the case of an individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton).

5. In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton) if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM <u>is not covered</u> if the initial BMM was performed by a dual-energy x-ray absorptiometry system (axial skeleton).

80.5.5 - Frequency Standards

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Medicare pays for a screening BMM once every 2 years (at least 23 months have passed since the month the last covered BMM was performed).

When medically necessary, Medicare may pay for more frequent BMMs. Examples include, but are not limited to, the following medical circumstances:

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- Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

- Confirming baseline BMMs to permit monitoring of beneficiaries in the future.

80.5.6 - Beneficiaries Who May be Covered

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

To be covered, a beneficiary must meet at least one of the five conditions listed below:

1. A woman who has been determined by the physician or qualified nonphysician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

   NOTE: Since not every woman who has been prescribed estrogen replacement therapy (ERT) may be receiving an “adequate” dose of the therapy, the fact that a woman is receiving ERT should not preclude her treating physician or other qualified treating nonphysician practitioner from ordering a bone mass measurement for her. If a BMM is ordered for a woman following a careful evaluation of her medical need, however, it is expected that the ordering treating physician (or other qualified treating

nonphysician practitioner) will document in her medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.

2. An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

3. An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day, for more than 3 months.

4. An individual with primary hyperparathyroidism.

5. An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

80.5.7 - Noncovered BMMs

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

The following BMMs are noncovered under Medicare because they are not considered reasonable and necessary under section 1862(a)(1)(A) of the Act.

- Single photon absorptiometry (effective January 1, 2007).
- Dual photon absorptiometry (established in 1983).

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80.5.8 - Claims Processing

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

For instructions concerning payment methodology, HCPCS coding, and Medicare summary notice and remittance advice messages, see chapter 13, section 140 of Pub. 100-04, Medicare Claims Processing Manual.

80.5.9 - National Coverage Determinations (NCDs)

(Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

In addition to these conditions for coverage, CMS may determine through the NCD process that additional BMM systems are reasonable and necessary under section 1862(a)(1) of the Act for monitoring and confirming baseline BMMs.

80.6 - Requirements for Ordering and Following Orders for Diagnostic Tests

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

The following sections provide instructions about ordering diagnostic tests and for complying with such orders for Medicare payment.

NOTE: Unless specified, these sections are not applicable in a hospital setting.

80.6.1 - Definitions

(Rev. 94, Issued: 08-29-08, Effective: 01-01-03, Implementation: 09-30-08)

Diagnostic Test

A "diagnostic test" includes all diagnostic x-ray tests, all diagnostic laboratory tests, and other diagnostic tests furnished to a beneficiary.

Treating Physician

A "treating physician" is a physician, as defined in §1861(r) of the Social Security Act (the Act), who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results of a diagnostic test in the management of the beneficiary's specific medical problem.

A radiologist performing a therapeutic interventional procedure is considered a treating physician. A radiologist performing a diagnostic interventional or diagnostic procedure is not considered a treating physician.

Treating Practitioner

A "treating practitioner" is a nurse practitioner, clinical nurse specialist, or physician assistant, as defined in §1861(s)(2)(K) of the Act, who furnishes, pursuant to State law, a consultation or treats a beneficiary for a specific medical problem, and who uses the result of a diagnostic test in the management of the beneficiary's specific medical problem.

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Testing Facility

A "testing facility" is a Medicare provider or supplier that furnishes diagnostic tests. A testing facility may include a physician or a group of physicians (e.g., radiologist, pathologist), a laboratory, or an independent diagnostic testing facility (IDTF).

Order

An "order" is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields to a certain value determined by the treating physician/practitioner (e.g., if test X is negative, then perform test Y). An order may be delivered via the following forms of communication:

- A written document signed by the treating physician/practitioner, which is hand-delivered, mailed, or faxed to the testing facility; **NOTE:** No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical

laboratory fee schedule, the physician fee schedule, or for physician pathology services;

- A telephone call by the treating physician/practitioner or his/her office to the testing facility; and

- An electronic mail by the treating physician/practitioner or his/her office to the testing facility.

If the order is communicated via telephone, both the treating physician/practitioner or his/her office, and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records. While a physician order is not required to be signed, the physician must clearly document, in the medical record, his or her intent that the test be performed.

80.6.2 - Interpreting Physician Determines a Different Diagnostic Test is Appropriate

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

When an interpreting physician, e.g., radiologist, cardiologist, family practitioner, general internist, neurologist, obstetrician, gynecologist, ophthalmologist, thoracic surgeon, vascular surgeon, at a testing facility determines that an ordered diagnostic radiology test is clinically inappropriate or suboptimal, and that a different diagnostic test should be performed (e.g., an MRI should be performed instead of a CT scan because of the clinical indication), the interpreting physician/testing facility may not perform the unordered test until a new order from the treating physician/practitioner has been received. Similarly, if the result of an ordered diagnostic test is normal and the interpreting physician believes that another diagnostic test should be performed (e.g., a renal sonogram was normal and based on the clinical indication, the interpreting physician believes an MRI will reveal the diagnosis), an order from the treating physician must be received prior to performing the unordered diagnostic test.

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80.6.3 - Rules for Testing Facility to Furnish Additional Tests

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

If the testing facility cannot reach the treating physician/practitioner to change the order or obtain a new order and documents this in the medical record, then the testing facility may furnish the additional diagnostic test if all of the following criteria apply:

- The testing center performs the diagnostic test ordered by the treating physician/practitioner;

- The interpreting physician at the testing facility determines and documents that, because of the abnormal result of the diagnostic test performed, an additional diagnostic test is medically necessary;

- Delaying the performance of the additional diagnostic test would have an adverse effect on the care of the beneficiary;

- The result of the test is communicated to and is used by the treating physician/practitioner in the treatment of the beneficiary; and

- The interpreting physician at the testing facility documents in his/her report why additional testing was done.

EXAMPLE:

The last cut of an abdominal CT scan with contrast shows a mass requiring a pelvic CT scan to further delineate the mass; (b) a bone scan reveals a lesion on the femur requiring plain films to make a diagnosis.

80.6.4 - Rules for Testing Facility Interpreting Physician to Furnish Different or Additional Tests

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

The following applies to an interpreting physician of a testing facility who furnishes a diagnostic test to a beneficiary who is not a hospital inpatient or outpatient. The interpreting physician must document accordingly in his/her report to the treating physician/practitioner.

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Test Design

Unless specified in the order, the interpreting physician may determine, without notifying the treating physician/practitioner, the parameters of the diagnostic test (e.g., number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media).

Clear Error

The interpreting physician may modify, without notifying the treating physician/practitioner, an order with clear and obvious errors that would be apparent to a reasonable layperson, such as the patient receiving the test (e.g., x-ray of wrong foot ordered).

Patient Condition

The interpreting physician may cancel, without notifying the treating physician/ practitioner, an order because the beneficiary's physical condition at the time of diagnostic testing will not permit performance of the test (e.g., a barium enema cannot be performed because of residual stool in colon on scout KUB; 170.5PA/LAT of the chest cannot be performed because the patient is unable to stand). When an ordered diagnostic

test is cancelled, any medically necessary preliminary or scout testing performed is payable.

80.6.5 - Surgical/Cytopathology Exception

(Rev. 80; Issued: 01-11-08; Effective: 01-01-03; Implementation: 11-19-07)

This exception applies to an independent laboratory's pathologist or a hospital pathologist who furnishes a pathology service to a beneficiary who is not a hospital inpatient or outpatient, and where the treating physician/practitioner does not specifically request additional tests the pathologist may need to perform. When a surgical or cytopathology specimen is sent to the pathology laboratory, it typically comes in a labeled container with a requisition form that reveals the patient demographics, the name of the physician/practitioner, and a clinical impression and/or brief history. There is no specific order from the surgeon or the treating physician/practitioner for a certain type of pathology service. While the pathologist will generally perform some type of examination or interpretation on the cells or tissue, there may be additional tests, such as special stains, that the pathologist may need to perform, even though they have not been specifically requested by the treating physician/practitioner. The pathologist may perform such additional tests under the following circumstances:

- These services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;
- The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and
- The pathologist documents in his/her report why additional testing was done.

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EXAMPLE:

A lung biopsy is sent by the surgeon to the pathology department, and the pathologist finds a granuloma which is suspicious for tuberculosis. The pathologist cultures the granuloma, sends it to bacteriology, and requests smears for acid fast bacilli (tuberculosis). The pathologist is expected to determine the need for these studies so that the surgical pathology examination and interpretation can be completed and the definitive diagnosis reported to the treating physician for use in treating the beneficiary.

90 - X-Ray, Radium, and Radioactive Isotope Therapy

(Rev. 1, 10-01-03)
B3-2075

These services also include materials and services of technicians.

X-ray, radium, and radioactive isotope therapy furnished in a nonprovider facility require direct personal supervision of a physician. The physician need not be in the same room, but must be in the area and immediately available to provide assistance and direction

throughout the time the procedure is being performed. This level of physician involvement does not represent a physician's service and cannot be billed as a Part B service. The physician would have to furnish a reasonable and necessary professional service as defined in §§30 of this chapter, in order for the physician's activity to be covered.

However, effective for radiation therapy services furnished on or after April 1, 1989, radiologists' weekly treatment management services are covered.

A separate charge for the services of a physicist is not recognized unless such services are covered under the "incident to" provision (§60.1 of this chapter) or the services are included as part of a technical component service billed by a freestanding radiation therapy center. The incident to provision may also be extended to include all necessary and appropriate services supplied by a radiation physicist assisting a radiologist when the physicist is in the physician's employ and working under his or her direct supervision.

100 - Surgical Dressings, Splints, Casts, and Other Devices Used for Reductions of Fractures and Dislocations

(Rev. 1, 10-01-03)
B3-2079, A3-3110.3, HO-228.3,

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Surgical dressings are limited to primary and secondary dressings required for the treatment of a wound caused by, or treated by, a surgical procedure that has been performed by a physician or other health care professional to the extent permissible under State law. In addition, surgical dressings required after debridement of a wound are also covered, irrespective of the type of debridement, as long as the debridement was reasonable and necessary and was performed by a health care professional acting within the scope of his/her legal authority when performing this function. Surgical dressings are covered for as long as they are medically necessary.

Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. Items such as adhesive tape, roll gauze, bandages, and disposable compression material are examples of secondary dressings. Elastic stockings, support hose, foot coverings, leotards, knee supports, surgical leggings, gauntlets, and pressure garments for the arms and hands are examples of items that are not ordinarily covered as surgical dressings. Some items, such as transparent film, may be used as a primary or secondary dressing.

If a physician, certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner. (See §§60.1, 180, 190, 200, and 210.) When surgical dressings are not covered incident to the services of a health care practitioner and are obtained by the patient from a supplier (e.g., a drugstore, physician, or other health care

practitioner that qualifies as a supplier) on an order from a physician or other health care professional authorized under State law or regulation to make such an order, the surgical dressings are covered separately under Part B.

Splints and casts, and other devices used for reductions of fractures and dislocations are covered under Part B of Medicare. This includes dental splints.

110 - Durable Medical Equipment - General

(Rev. 1, 10-01-03)
B3-2100, A3-3113, HO-235, HHA-220

Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient's home.

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The decision whether to rent or purchase an item of equipment generally resides with the beneficiary, but the decision on how to pay rests with CMS. For some DME, program payment policy calls for lump sum payments and in others for periodic payment. Where covered DME is furnished to a beneficiary by a supplier of services other than a provider of services, the DMERC makes the reimbursement. If a provider of services furnishes the equipment, the intermediary makes the reimbursement. The payment method is identified in the annual fee schedule update furnished by CMS.

The CMS issues quarterly updates to a fee schedule file that contains rates by HCPCS code and also identifies the classification of the HCPCS code within the following categories.

Category Code	Definition
IN	Inexpensive and Other Routinely Purchased Items
FS	Frequently Serviced Items
CR	Capped Rental Items
OX	Oxygen and Oxygen Equipment
OS	Ostomy, Tracheostomy & Urological Items

Category Code	Definition
SD	Surgical Dressings
PO	Prosthetics & Orthotics
SU	Supplies
TE	Transcutaneous Electrical Nerve Stimulators

The DMERCs, carriers, and intermediaries, where appropriate, use the CMS files to determine payment rules. See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices," for a detailed description of payment rules for each classification.

Payment may also be made for repairs, maintenance, and delivery of equipment and for expendable and nonreusable items essential to the effective use of the equipment subject to the conditions in §110.2.

See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," for hemodialysis equipment and supplies.

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110.1 - Definition of Durable Medical Equipment

(Rev. 1, 10-01-03)
B3-2100.1, A3-3113.1, HO-235.1, HHA-220.1, B3-2100.2, A3-3113.2, HO-235.2, HHA-220.2

Durable medical equipment is equipment which:

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

All requirements of the definition must be met before an item can be considered to be durable medical equipment.

The following describes the underlying policies for determining whether an item meets the definition of DME and may be covered.

A. Durability

An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature, such as incontinent pads, lambs wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, irrigating kits, sheets, and bags are not considered "durable" within the meaning of the definition. There are other items that, although durable in nature, may fall into other coverage categories such as supplies, braces, prosthetic devices, artificial arms, legs, and eyes.

B. Medical Equipment

Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no development will be needed to determine whether a specific item of equipment is medical in nature. However, some cases will require development to determine whether the item constitutes medical equipment. This development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

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1. Equipment Presumptively Medical

Items such as hospital beds, wheelchairs, hemodialysis equipment, iron lungs, respirators, intermittent positive pressure breathing machines, medical regulators, oxygen tents, crutches, canes, trapeze bars, walkers, inhalators, nebulizers, commodes, suction machines, and traction equipment presumptively constitute medical equipment. (Although hemodialysis equipment is covered as a prosthetic device (§120), it also meets the definition of DME, and reimbursement for the rental or purchase of such equipment for use in the beneficiary's home will be made only under the provisions for payment applicable to DME. See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," §30.1, for coverage of home use of hemodialysis.) **NOTE:** There is a wide variety in types of respirators and suction machines. The DMERC's medical staff should determine whether the apparatus specified in the claim is appropriate for home use.

2. Equipment Presumptively Nonmedical

Equipment which is primarily and customarily used for a nonmedical purpose may not be considered "medical" equipment for which payment can be made under the medical insurance program. This is true even though the item has some remote medically related use. For example, in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless,

because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.

Other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered covered DME. These include, for example, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, and posture chairs, do not constitute medical equipment. Similarly, physical fitness equipment (such as an exercycle), first-aid or precautionary-type equipment (such as preset portable oxygen units), self-help devices (such as safety grab bars), and training equipment (such as Braille training texts) are considered nonmedical in nature.

3. Special Exception Items

Specified items of equipment may be covered under certain conditions even though they do not meet the definition of DME because they are not primarily and customarily used to serve a medical purpose and/or are generally useful in the absence of illness or injury. These items would be covered when it is clearly established that they serve a therapeutic purpose in an individual case and would include:

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a. Gel pads and pressure and water mattresses (which generally serve a preventive purpose) when prescribed for a patient who had bed sores or there is medical evidence indicating that they are highly susceptible to such ulceration, and

b. Heat lamps for a medical rather than a soothing or cosmetic purpose, e.g., where the need for heat therapy has been established.

In establishing medical necessity for the above items, the evidence must show that the item is included in the physician's course of treatment and a physician is supervising its use.

NOTE: The above items represent special exceptions and no extension of coverage to other items should be inferred

C. Necessary and Reasonable

Although an item may be classified as DME, it may not be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury, or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or

will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements;" §60, regarding the rules for providing advance beneficiary notices (ABNs) that advise beneficiaries, before items or services actually are furnished, when Medicare is likely to deny payment for them. ABNs allow beneficiaries to make an informed consumer decision about receiving items or services for which they may have to pay out-of-pocket and to be more active participants in their own health care treatment decisions.

1. Necessity for the Equipment

Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his or her malformed body member. In most cases the physician's prescription for the equipment and other medical information available to the DMERC will be sufficient to establish that the equipment serves this purpose.

2. Reasonableness of the Equipment

Even though an item of DME may serve a useful medical purpose, the DMERC or intermediary must also consider to what extent, if any, it would be reasonable for the Medicare program to pay for the item prescribed. The following considerations should enter into the determination of reasonableness:

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1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?

2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?

3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

3. Payment Consistent With What is Necessary and Reasonable

Where a claim is filed for equipment containing features of an aesthetic nature or features of a medical nature which are not required by the patient's condition or where there exists a reasonably feasible and medically appropriate alternative pattern of care which is less costly than the equipment furnished, the amount payable is based on the rate for the equipment or alternative treatment which meets the patient's medical needs.

The acceptance of an assignment binds the supplier-assignee to accept the payment for the medically required equipment or service as the full charge and the supplier-assignee

cannot charge the beneficiary the differential attributable to the equipment actually furnished.

4. Establishing the Period of Medical Necessity

Generally, the period of time an item of durable medical equipment will be considered to be medically necessary is based on the physician's estimate of the time that his or her patient will need the equipment. See the Medicare Program Integrity Manual, Chapters 5 and 6, for medical review guidelines.

D. Definition of a Beneficiary's Home

For purposes of rental and purchase of DME a beneficiary's home may be his/her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution. However, an institution may not be considered a beneficiary's home if it:

- Meets at least the basic requirement in the definition of a hospital, i.e., it is primarily engaged in providing by or under the supervision of physicians, to inpatients, diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, and sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or

- Meets at least the basic requirement in the definition of a skilled nursing facility, i.e., it is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

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Thus, if an individual is a patient in an institution or distinct part of an institution which provides the services described in the bullets above, the individual is not entitled to have separate Part B payment made for rental or purchase of DME. This is because such an institution may not be considered the individual's home. The same concept applies even if the patient resides in a bed or portion of the institution not certified for Medicare.

If the patient is at home for part of a month and, for part of the same month is in an institution that cannot qualify as his or her home, or is outside the U.S., monthly payments may be made for the entire month. Similarly, if DME is returned to the provider before the end of a payment month because the beneficiary died in that month or because the equipment became unnecessary in that month, payment may be made for the entire month.

110.2 - Repairs, Maintenance, Replacement, and Delivery
(Rev. 30, Issued 02-18-05, Effective/Implementation: Not Applicable)

Under the circumstances specified below, payment may be made for repair, maintenance, and replacement of medically required DME, including equipment which had been in use before the user enrolled in Part B of the program. However, do not pay for repair,

maintenance, or replacement of equipment in the frequent and substantial servicing or oxygen equipment payment categories. In addition, payments for repair and maintenance may not include payment for parts and labor covered under a manufacturer's or supplier's warranty.

A. Repairs

To repair means to fix or mend and to put the equipment back in good condition after damage or wear. Repairs to equipment which a beneficiary owns are covered when necessary to make the equipment serviceable. However, do not pay for repair of previously denied equipment or equipment in the frequent and substantial servicing or oxygen equipment payment categories. If the expense for repairs exceeds the estimated expense of purchasing or renting another item of equipment for the remaining period of medical need, no payment can be made for the amount of the excess. (See subsection C where claims for repairs suggest malicious damage or culpable neglect.)

Since renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for repair of rented equipment are not covered. This includes items in the frequent and substantial servicing, oxygen equipment, capped rental, and inexpensive or routinely purchased payment categories which are being rented.

A new Certificate of Medical Necessity (CMN) and/or physician's order is not needed for repairs.

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For replacement items, see Subsection C below.

B. Maintenance

Routine periodic servicing, such as testing, cleaning, regulating, and checking of the beneficiary's equipment, is not covered. The owner is expected to perform such routine maintenance rather than a retailer or some other person who charges the beneficiary. Normally, purchasers of DME are given operating manuals which describe the type of servicing an owner may perform to properly maintain the equipment. It is reasonable to expect that beneficiaries will perform this maintenance. Thus, hiring a third party to do such work is for the convenience of the beneficiary and is not covered. However, more extensive maintenance which, based on the manufacturers' recommendations, is to be performed by authorized technicians, is covered as repairs for medically necessary equipment which a beneficiary owns. This might include, for example, breaking down sealed components and performing tests which require specialized testing equipment not available to the beneficiary. Do not pay for maintenance of purchased items that require frequent and substantial servicing or oxygen equipment.

Since renters of equipment recover from the rental charge the expenses they incur in maintaining in working order the equipment they rent out, separately itemized charges for maintenance of rented equipment are generally not covered. Payment may not be made

for maintenance of rented equipment other than the maintenance and servicing fee established for capped rental items. For capped rental items which have reached the 15-month rental cap, contractors pay claims for maintenance and servicing fees after 6 months have passed from the end of the final paid rental month or from the end of the period the item is no longer covered under the supplier's or manufacturer's warranty, whichever is later. See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for additional instruction and an example.

A new CMN and/or physician's order is not needed for covered maintenance.

C. Replacement

Replacement refers to the provision of an identical or nearly identical item. Situations involving the provision of a different item because of a change in medical condition are not addressed in this section.

Equipment which the beneficiary owns or is a capped rental item may be replaced in cases of loss or irreparable damage. Irreparable damage refers to a specific accident or to a natural disaster (e.g., fire, flood). A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item.

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Irreparable wear refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified. Replacement of equipment due to irreparable wear takes into consideration the reasonable useful lifetime of the equipment. If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, the beneficiary may elect to obtain a new piece of equipment. Replacement may be reimbursed when a new physician order and/or new CMN, when required, is needed to reaffirm the medical necessity of the item.

The reasonable useful lifetime of durable medical equipment is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment, but in no case can it be less than 5 years. Computation of the useful lifetime is based on when the equipment is delivered to the beneficiary, not the age of the equipment. Replacement due to wear is not covered during the reasonable useful lifetime of the equipment. During the reasonable useful lifetime, Medicare does cover repair up to the cost of replacement (but not actual replacement) for medically necessary equipment owned by the beneficiary. (See subsection A.)

Charges for the replacement of oxygen equipment, items that require frequent and substantial servicing or inexpensive or routinely purchased items which are being rented are not covered.

Cases suggesting malicious damage, culpable neglect, or wrongful disposition of equipment should be investigated and denied where the DMERC determines that it is unreasonable to make program payment under the circumstances. DMERCs refer such cases to the program integrity specialist in the RO.

D. Delivery

Payment for delivery of DME whether rented or purchased is generally included in the fee schedule allowance for the item. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," for the rules that apply to making reimbursement for exceptional cases.

110.3 - Coverage of Supplies and Accessories

(Rev. 1, 10-01-03)
B3-2100.5, A3-3113.4, HO-235.4, HHA-220.5

Payment may be made for supplies, e.g., oxygen, that are necessary for the effective use of durable medical equipment. Such supplies include those drugs and biologicals which must be put directly into the equipment in order to achieve the therapeutic benefit of the durable medical equipment or to assure the proper functioning of the equipment, e.g., tumor chemotherapy agents used with an infusion pump or heparin used with a home dialysis system. However, the coverage of such drugs or biologicals does not preclude the need for a determination that the drug or biological itself is reasonable and necessary for treatment of the illness or injury or to improve the functioning of a malformed body member.

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In the case of prescription drugs, other than oxygen, used in conjunction with durable medical equipment, prosthetic, orthotics, and supplies (DMEPOS) or prosthetic devices, the entity that dispenses the drug must furnish it directly to the patient for whom a prescription is written. The entity that dispenses the drugs must have a Medicare supplier number, must possess a current license to dispense prescription drugs in the State in which the drug is dispensed, and must bill and receive payment in its own name. A supplier that is not the entity that dispenses the drugs cannot purchase the drugs used in conjunction with DME for resale to the beneficiary. Reimbursement may be made for replacement of essential accessories such as hoses, tubes, mouthpieces, etc., for necessary DME, only if the beneficiary owns or is purchasing the equipment.

110.4 - Miscellaneous Issues Included in the Coverage of Equipment

(Rev. 1, 10-01-03)
B3-2100.6, A3-3113.5, HO-235.5, HHA-220.6

Payment can be made for the purchase of DME even though rental payments may have been made for prior months. This could occur where, because of a change in his/her condition, the beneficiary feels that it would be to his/her advantage to purchase the equipment rather than to continue to rent it.

A beneficiary may sell or otherwise dispose of equipment for which they have no further use, for example, because of recovery from the illness or injury that gave rise to the need for the equipment. (There is no authority for the program to repossess the equipment.) If after such disposal there is again medical need for similar equipment, payment can be made for the rental or purchase of that equipment.

However, where an arrangement is motivated solely by a desire to create artificial expenses to be met by the program and to realize a profit thereby, such expenses would not be covered under the program. The resolution of questions involving the disposition and subsequent acquisition of durable medical equipment must be made on a case-by-case basis.

Cases where it appears that there has been an attempt to create an artificial expense and realize a profit thereby should be developed and when appropriate denied. After adjudication the DMERC would refer such cases to the program integrity specialist in the RO.

When payments stop because the beneficiary's condition has changed and the equipment is no longer medically necessary, the beneficiary is responsible for the remaining noncovered charges. Similarly, when payments stop because the beneficiary dies, the beneficiary's estate is responsible for the remaining noncovered charges.

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Contractors do not get involved in issues relating to ownership or title of property.

110.5 - Incurred Expense Dates for Durable Medical Equipment

(Rev. 1, 10-01-03)
A3-3113.7.B, HO-235.7.B, B3-3011

The date of service on the claim must be the date that the beneficiary or authorized representative received the DMEPOS item. If the date of delivery is not specified on the bill, the contractor should assume, in the absence of evidence to the contrary, that the date of purchase was the date of delivery.

For mail order DMEPOS items, the date of service on the claim must be the shipping date.

The date of service on the claim must be the date that the DMEPOS item(s) was received by the nursing facility if the supplier delivered it or the shipping date if the supplier utilized a delivery/shipping service.

An exception to the preceding statements concerning the date of service on the claim occurs when items are provided in anticipation of discharge from a hospital or nursing facility. If a DMEPOS item is delivered to a patient in a hospital up to two days prior to discharge to home and it is for the benefit of the patient for purposes of fitting or training

of the patient on its use, the supplier should bill the date of service on the claim as the date of discharge to home and should use POS=12.

See the Medicare Program Integrity Manual, Chapter 5, “Items and Services Having Special DMERC Review Considerations,” for additional information pertaining to the date of service on the claim. Also see the Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Surgical dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices,” for additional DME billing and claims processing information.

110.6 - Determining Months for Which Periodic Payments May Be Made for Equipment Used in an Institution

(Rev. 1, 10-01-03)
A3-3113.7.D, HO-235.7.C

If a patient uses equipment subject to the monthly payment rule in an institution, which does not qualify as his or her home, the used months during which the beneficiary was institutionalized are not covered.

110.7 - No Payment for Purchased Equipment Delivered Outside the United States or Before Beneficiary’s Coverage Began

(Rev. 1, 10-01-03)
A3-3113.7.C

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In the case of equipment subject to the lump sum payment rules, the beneficiary must have been in the United States and must have had Medicare coverage at the time the item was delivered. Therefore, where an item of durable medical equipment paid for as a lump sum was delivered to an individual outside the United States or before his or her coverage period began, the entire expense of the item would be excluded from coverage. Payment cannot be made in such cases even though the individual later uses the item inside the United States or after his or her coverage begins.

If the individual is outside the U.S. for more than 30 days and then returns to the U.S., the DMERC determines medical necessity as in an initial case before resuming payments.

120 - Prosthetic Devices

(Rev. 1, 10-01-03)
B3-2130, A3-3110.4, HO-228.4, A3-3111, HO-229

A. General

Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or replace all or part of the function of a permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician’s order. This does not require a determination that there is no possibility that the patient’s condition may improve sometime in the future. If the medical record,

including the judgment of the attending physician, indicates the condition is of long and indefinite duration, the test of permanence is considered met. (Such a device may also be covered under §60.l as a supply when furnished incident to a physician's service.)

Examples of prosthetic devices include artificial limbs, parenteral and enteral (PEN) nutrition, cardiac pacemakers, prosthetic lenses (see subsection B), breast prostheses (including a surgical brassiere) for postmastectomy patients, maxillofacial devices, and devices which replace all or part of the ear or nose. A urinary collection and retention system with or without a tube is a prosthetic device replacing bladder function in case of permanent urinary incontinence. The foley catheter is also considered a prosthetic device when ordered for a patient with permanent urinary incontinence. However, chucks, diapers, rubber sheets, etc., are supplies that are not covered under this provision. Although hemodialysis equipment is a prosthetic device, payment for the rental or purchase of such equipment in the home is made only for use under the provisions for payment applicable to durable medical equipment.

An exception is that if payment cannot be made on an inpatient's behalf under Part A, hemodialysis equipment, supplies, and services required by such patient could be covered under Part B as a prosthetic device, which replaces the function of a kidney. See the Medicare Benefit Policy Manual, Chapter 11, "End Stage Renal Disease," for payment for hemodialysis equipment used in the home. See the Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §10, for additional instructions on hospitalization for renal dialysis.

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NOTE: Medicare does not cover a prosthetic device dispensed to a patient prior to the time at which the patient undergoes the procedure that makes necessary the use of the device. For example, the carrier does not make a separate Part B payment for an intraocular lens (IOL) or pacemaker that a physician, during an office visit prior to the actual surgery, dispenses to the patient for his or her use. Dispensing a prosthetic device in this manner raises health and safety issues. Moreover, the need for the device cannot be clearly established until the procedure that makes its use possible is successfully performed. Therefore, dispensing a prosthetic device in this manner is not considered reasonable and necessary for the treatment of the patient's condition.

Colostomy (and other ostomy) bags and necessary accouterments required for attachment are covered as prosthetic devices. This coverage also includes irrigation and flushing equipment and other items and supplies directly related to ostomy care, whether the attachment of a bag is required.
Accessories and/or supplies which are used directly with an enteral or parenteral device to achieve the therapeutic benefit of the prosthesis or to assure the proper functioning of the device may also be covered under the prosthetic device benefit subject to the additional guidelines in the Medicare National Coverage Determinations Manual.

Covered items include catheters, filters, extension tubing, infusion bottles, pumps (either food or infusion), intravenous (I.V.) pole, needles, syringes, dressings, tape, Heparin Sodium (parenteral only), volumetric monitors (parenteral only), and parenteral and

enteral nutrient solutions. Baby food and other regular grocery products that can be blenderized and used with the enteral system are not covered. Note that some of these items, e.g., a food pump and an I.V. pole, qualify as DME. Although coverage of the enteral and parenteral nutritional therapy systems is provided on the basis of the prosthetic device benefit, the payment rules relating to lump sum or monthly payment for DME apply to such items.

The coverage of prosthetic devices includes replacement of and repairs to such devices as explained in subsection D.

Finally, the Benefits Improvement and Protection Act of 2000 amended §1834(h)(1) of the Act by adding a provision (1834 (h)(1)(G)(i)) that requires Medicare payment to be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is necessary.

Payment may be made for the replacement of a prosthetic device that is an artificial limb, or replacement part of a device if the ordering physician determines that the replacement device or part is necessary because of any of the following:

1. A change in the physiological condition of the patient;

2. An irreparable change in the condition of the device, or in a part of the device; or

3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

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This provision is effective for items replaced on or after April 1, 2001. It supersedes any rule that that provided a 5-year or other replacement rule with regard to prosthetic devices.

B. Prosthetic Lenses

The term "internal body organ" includes the lens of an eye. Prostheses replacing the lens of an eye include post-surgical lenses customarily used during convalescence from eye surgery in which the lens of the eye was removed. In addition, permanent lenses are also covered when required by an individual lacking the organic lens of the eye because of surgical removal or congenital absence. Prosthetic lenses obtained on or after the beneficiary's date of entitlement to supplementary medical insurance benefits may be covered even though the surgical removal of the crystalline lens occurred before entitlement.

1. Prosthetic Cataract Lenses

One of the following prosthetic lenses or combinations of prosthetic lenses furnished by a physician (see **§30.4** for coverage of prosthetic lenses prescribed by a doctor of optometry) may be covered when determined to be reasonable and necessary to restore essentially the vision provided by the crystalline lens of the eye:

- Prosthetic bifocal lenses in frames;
- Prosthetic lenses in frames for far vision, and prosthetic lenses in frames for near vision; or
- When a prosthetic contact lens(es) for far vision is prescribed (including cases of binocular and monocular aphakia), make payment for the contact lens(es) and prosthetic lenses in frames for near vision to be worn at the same time as the contact lens(es), and prosthetic lenses in frames to be worn when the contacts have been removed.

Lenses which have ultraviolet absorbing or reflecting properties may be covered, in lieu of payment for regular (untinted) lenses, if it has been determined that such lenses are medically reasonable and necessary for the individual patient.

Medicare does not cover cataract sunglasses obtained in addition to the regular (untinted) prosthetic lenses since the sunglasses duplicate the restoration of vision function performed by the regular prosthetic lenses.

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2. Payment for Intraocular Lenses (IOLs) Furnished in Ambulatory Surgical Centers (ASCs)

Effective for services furnished on or after March 12, 1990, payment for intraocular lenses (IOLs) inserted during or subsequent to cataract surgery in a Medicare certified ASC is included with the payment for facility services that are furnished in connection with the covered surgery.

Refer to the Medicare Claims Processing Manual, Chapter 14, “Ambulatory Surgical Centers,” for more information.

3. Limitation on Coverage of Conventional Lenses

One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery with insertion of an IOL is covered.

C. Dentures

Dentures are excluded from coverage. However, when a denture or a portion of the denture is an integral part (built-in) of a covered prosthesis (e.g., an obturator to fill an opening in the palate), it is covered as part of that prosthesis.

D. Supplies, Repairs, Adjustments, and Replacement

Supplies are covered that are necessary for the effective use of a prosthetic device (e.g., the batteries needed to operate an artificial larynx). Adjustment of prosthetic devices required by wear or by a change in the patient's condition is covered when ordered by a physician. General provisions relating to the repair and replacement of durable medical equipment in §110.2 for the repair and replacement of prosthetic devices are applicable. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §40.4, for payment for devices replaced under a warranty.) Replacement of conventional eyeglasses or contact lenses furnished in accordance with §120.B.3 is not covered.

Necessary supplies, adjustments, repairs, and replacements are covered even when the device had been in use before the user enrolled in Part B of the program, so long as the device continues to be medically required.

130 - Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes

(Rev. 1, 10-01-03)
B3-2133, A3-3110.5, HO-228.5, AB-01-06 dated 1/18/01

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These appliances are covered under Part B when furnished incident to physicians' services or on a physician's order. A brace includes rigid and semi-rigid devices which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. Elastic stockings, garter belts, and similar devices do not come within the scope of the definition of a brace. Back braces include, but are not limited to, special corsets, e.g., sacroiliac, sacrolumbar, dorsolumbar corsets, and belts. A terminal device (e.g., hand or hook) is covered under this provision whether an artificial limb is required by the patient. Stump stockings and harnesses (including replacements) are also covered when these appliances are essential to the effective use of the artificial limb.

Adjustments to an artificial limb or other appliance required by wear or by a change in the patient's condition are covered when ordered by a physician.

Adjustments, repairs and replacements are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

140 - Therapeutic Shoes for Individuals with Diabetes

(Rev. 1, 10-01-03)
B3-2134

Coverage of therapeutic shoes (depth or custom-molded) along with inserts for individuals with diabetes is available as of May 1, 1993. These diabetic shoes are covered if the requirements as specified in this section concerning certification and

prescription are fulfilled. In addition, this benefit provides for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease. Each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected. Claims for therapeutic shoes for diabetics are processed by the Durable Medical Equipment Regional Carriers (DMERCs).

Therapeutic shoes for diabetics are not DME and are not considered DME nor orthotics, but a separate category of coverage under Medicare Part B. (See §1861(s)(12) and §1833(o) of the Act.)

A. Definitions

The following items may be covered under the diabetic shoe benefit:

1. Custom-Molded Shoes

Custom-molded shoes are shoes that:

- Are constructed over a positive model of the patient's foot;
- Are made from leather or other suitable material of equal quality;
- Have removable inserts that can be altered or replaced as the patient's condition warrants; and
- Have some form of shoe closure.

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2. Depth Shoes

Depth shoes are shoes that:

- Have a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts;
- Are made from leather or other suitable material of equal quality;
- Have some form of shoe closure; and
- Are available in full and half sizes with a minimum of three widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)

3. Inserts

Inserts are total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot and that are made of a suitable material with regard to the patient's condition.

B. Coverage

1. Limitations

For each individual, coverage of the footwear and inserts is limited to one of the following within one calendar year:

- No more than one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts; or

- No more than one pair of depth shoes and three pairs of inserts (not including the noncustomized removable inserts provided with such shoes).

2. Coverage of Diabetic Shoes and Brace

Orthopedic shoes, as stated in the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices," generally are not covered. This exclusion does not apply to orthopedic shoes that are an integral part of a leg brace. In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately. Thus, the diabetic shoes may be covered if the requirements for this section are met, while the brace may be covered if the requirements of §130 are met.

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3. Substitution of Modifications for Inserts

An individual may substitute modification(s) of custom-molded or depth shoes instead of obtaining a pair(s) of inserts in any combination. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled. The following is a list of the most common shoe modifications available, but it is not meant as an exhaustive list of the modifications available for diabetic shoes:

- **Rigid Rocker Bottoms -** These are exterior elevations with apex positions for 51 percent to 75 percent distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapered off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel;

- **Roller Bottoms (Sole or Bar)** - These are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole;

- **Metatarsal Bars** - An exterior bar is placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose;

- **Wedges (Posting)** - Wedges are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance; and

- **Offset Heels** - This is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

Other modifications to diabetic shoes include, but are not limited to flared heels, Velcro closures, and inserts for missing toes.

4. Separate Inserts

Inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found above for depth shoes and custom-molded shoes.

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C. Certification

The need for diabetic shoes must be certified by a physician who is a doctor of medicine or a doctor of osteopathy and who is responsible for diagnosing and treating the patient's diabetic systemic condition through a comprehensive plan of care. This managing physician must:

- Document in the patient's medical record that the patient has diabetes;

- Certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and

- Document in the patient's record that the patient has one or more of the following conditions:

    - Peripheral neuropathy with evidence of callus formation;

    - History of pre-ulcerative calluses;

    - History of previous ulceration;

- Foot deformity;
- Previous amputation of the foot or part of the foot; or
- Poor circulation.

D. Prescription

Following certification by the physician managing the patient's systemic diabetic condition, a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts may prescribe the particular type of footwear necessary.

E. Furnishing Footwear

The footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, an orthotist, or a prosthetist. The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area. It is left to the discretion of each carrier to determine the meaning of "in the area."

150 - Dental Services

(Rev. 1, 10-01-03)
B3-2136

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As indicated under the general exclusions from coverage, items and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth are not covered. "Structures directly supporting the teeth" means the periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process.

In addition to the following, see Pub 100-01, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, Definitions and Pub 3, the Medicare National Coverage Determinations Manual for specific services which may be covered when furnished by a dentist. If an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion is covered.

EXAMPLE 1:

The reconstruction of a ridge performed primarily to prepare the mouth for dentures is a noncovered procedure. However, when the reconstruction of a ridge is performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service.

EXAMPLE 2:

Medicare makes payment for the wiring of teeth when this is done in connection with the reduction of a jaw fracture.

The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also covered. This is an exception to the requirement that to be covered, a noncovered procedure or service performed by a dentist must be an incident to and an integral part of a covered procedure or service performed by the dentist. Ordinarily, the dentist extracts the patient's teeth, but another physician, e.g., a radiologist, administers the radiation treatments.

When an excluded service is the primary procedure involved, it is not covered, regardless of its complexity or difficulty. For example, the extraction of an impacted tooth is not covered. Similarly, an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy are excluded from coverage when either of these procedures is performed in connection with an excluded service, e.g., the preparation of the mouth for dentures. In a like manner, the removal of a torus palatinus (a bony protuberance of the hard palate) may be a covered service. However, with rare exception, this surgery is performed in connection with an excluded service, i.e., the preparation of the mouth for dentures. Under such circumstances, Medicare does not pay for this procedure.

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Dental splints used to treat a dental condition are excluded from coverage under 1862(a)(12) of the Act. On the other hand, if the treatment is determined to be a covered medical condition (i.e., dislocated upper/lower jaw joints), then the splint can be covered.

Whether such services as the administration of anesthesia, diagnostic x-rays, and other related procedures are covered depends upon whether the primary procedure being performed by the dentist is itself covered. Thus, an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered. However, a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered.

Medicare makes payment for a covered dental procedure no matter where the service is performed. The hospitalization or nonhospitalization of a patient has no direct bearing on the coverage or exclusion of a given dental procedure.

Payment may also be made for services and supplies furnished incident to covered dental services. For example, the services of a dental technician or nurse who is under the direct supervision of the dentist or physician are covered if the services are included in the dentist's or physician's bill.

150.1 - Treatment of Temporomandibular Joint (TMJ) Syndrome

(Rev. 1, 10-01-03)
PASS memo Read.014

There are a wide variety of conditions that can be characterized as TMJ, and an equally wide variety of methods for treating these conditions. Many of the procedures fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services and appliances used to treat TMJ fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment "for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth...." For these reasons, a diagnosis of TMJ on a claim is insufficient. The actual condition or symptom must be determined.

160 - Clinical Psychologist Services

(Rev. 51, Issued: 06-23-06, Effective: 01-01-05, Implementation: 09-21-06)

A. Clinical Psychologist (CP) Defined

To qualify as a clinical psychologist (CP), a practitioner must meet the following requirements:

Hold a doctoral degree in psychology;

Be licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

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B. Qualified Clinical Psychologist Services Defined

Effective July 1, 1990, the diagnostic and therapeutic services of CPs and services and supplies furnished incident to such services are covered as the services furnished by a physician or as incident to physician's services are covered. However, the CP must be legally authorized to perform the services under applicable licensure laws of the State in which they are furnished.

C. Types of Clinical Psychologist Services That May Be Covered

Diagnostic and therapeutic services that the CP is legally authorized to perform in accordance with State law and/or regulation. Carriers pay all qualified CPs based on the physician fee schedule for the diagnostic and therapeutic services. (Psychological tests by practitioners who do not meet the requirements for a CP may be covered under the provisions for diagnostic tests as described in §80.2.

Services and supplies furnished incident to a CP's services are covered if the requirements that apply to services incident to a physician's services, as described in §60 are met. These services must be:

- Mental health services that are commonly furnished in CPs' offices;

- An integral, although incidental, part of professional services performed by the CP;

- Performed under the direct personal supervision of the CP; i.e., the CP must be physically present and immediately available;

- Furnished without charge or included in the CP's bill; and

- Performed by an employee of the CP (or an employee of the legal entity that employs the supervising CP) under the common law control test of the Act, as set forth in 20 CFR 404.1007 and §RS 2101.020 of the Retirement and Survivors Insurance part of the Social Security Program Operations Manual System.

- Diagnostic psychological testing services when furnished under the general supervision of a CP.

Carriers are required to familiarize themselves with appropriate State laws and/or regulations governing a CP's scope of practice.

D. Noncovered Services

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The services of CPs are not covered if the service is otherwise excluded from Medicare coverage even though a clinical psychologist is authorized by State law to perform them. For example, §1862(a)(1)(A) of the Act excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member." Therefore, even though the services are authorized by State law, the services of a CP that are determined to be not reasonable and necessary are not covered. Additionally, any therapeutic services that are billed by CPs under CPT psychotherapy codes that include medical evaluation and management services are not covered.

E. Requirement for Consultation

When applying for a Medicare provider number, a CP must submit to the carrier a signed Medicare provider/supplier enrollment form that indicates an agreement to the effect that, contingent upon the patient's consent, the CP will attempt to consult with the patient's attending or primary care physician in accordance with accepted professional ethical norms, taking into consideration patient confidentiality.

If the patient assents to the consultation, the CP must attempt to consult with the patient's physician within a reasonable time after receiving the consent. If the CP's attempts to consult directly with the physician are not successful, the CP must notify the physician within a reasonable time that he or she is furnishing services to the patient. Additionally, the CP must document, in the patient's medical record, the date the patient consented or

declined consent to consultations, the date of consultation, or, if attempts to consult did not succeed, that date and manner of notification to the physician.

The only exception to the consultation requirement for CPs is in cases where the patient's primary care or attending physician refers the patient to the CP. Also, neither a CP nor a primary care nor attending physician may bill Medicare or the patient for this required consultation.

F. Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CPs are subject to the outpatient mental health services limitation in Pub 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

G. Assignment Requirement
Assignment is required.

170 - Clinical Social Worker (CSW) Services
(Rev. 1, 10-01-03)
B3-2152

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See the Medicare Claims Processing Manual Chapter 12, Physician/Nonphysician Practitioners, §150, "Clinical Social Worker Services," for payment requirements.

A. Clinical Social Worker Defined

Section 1861(hh) of the Act defines a "clinical social worker" as an individual who:

- Possesses a master's or doctor's degree in social work;
- Has performed at least two years of supervised clinical social work; and
- Is licensed or certified as a clinical social worker by the State in which the services are performed; or
- In the case of an individual in a State that does not provide for licensure or certification, has completed at least 2 years or 3,000 hours of post master's degree supervised clinical social work practice under the supervision of a master's level social worker in an appropriate setting such as a hospital, SNF, or clinic.

B. Clinical Social Worker Services Defined

Section 1861(hh)(2) of the Act defines "clinical social worker services" as those services that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed for the diagnosis and treatment of mental illnesses. Services furnished to an inpatient of a hospital or an inpatient of a SNF that the SNF is required to provide as a requirement for participation are not included. The services that are covered are those that are otherwise covered if furnished by a physician or as incident to a physician's professional service.

C. Covered Services

Coverage is limited to the services a CSW is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law). The services of a CSW may be covered under Part B if they are:

- The type of services that are otherwise covered if furnished by a physician, or as incident to a physician's service. (See §30 for a description of physicians' services and §70 of Pub 100-1, the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 5, for the definition of a physician.);

- Performed by a person who meets the definition of a CSW (See subsection A.); and

- Not otherwise excluded from coverage.

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Carriers should become familiar with the State law or regulatory mechanism governing a CSW's scope of practice in their service area.

D. Noncovered Services

Services of a CSW are not covered when furnished to inpatients of a hospital or to inpatients of a SNF if the services furnished in the SNF are those that the SNF is required to furnish as a condition of participation in Medicare. In addition, CSW services are not covered if they are otherwise excluded from Medicare coverage even though a CSW is authorized by State law to perform them. For example, the Medicare law excludes from coverage services that are not "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."

E. Outpatient Mental Health Services Limitation

All covered therapeutic services furnished by qualified CSWs are subject to the outpatient psychiatric services limitation in Pub 100-01, Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30, (i.e., only 62 1/2 percent of expenses for these services are considered incurred expenses for Medicare purposes). The limitation does not apply to diagnostic services.

F. Assignment Requirement

Assignment is required.

180 - Nurse-Midwife (CNM) Services

(Rev. 1, 10-01-03)
B3-2154

A. General

Effective on or after July 1, 1988, the services provided by a certified nurse-midwife or incident to the certified nurse-midwife's services are covered. Payment is made under assignment only.

See the Medicare Claims Processing Manual, Chapter 12, "Physician and Nonphysician Practitioners," §130, for payment methodology for nurse midwife services.

B. Certified Nurse-Midwife Defined

A certified nurse-midwife is a registered nurse who has successfully completed a program of study and clinical experience in nurse-midwifery, meeting guidelines prescribed by the Secretary, or who has been certified by an organization recognized by the Secretary. The Secretary has recognized certification by the American College of Nurse-Midwives and State qualifying requirements in those States that specify a program of education and clinical experience for nurse-midwives for these purposes. A nurse-midwife must:

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- Be currently licensed to practice in the State as a registered professional nurse; and

- Meet one of the following requirements:

    1. Be legally authorized under State law or regulations to practice as a nurse-midwife and have completed a program of study and clinical experience for nurse-midwives, as specified by the State; or

    2. If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, the nurse-midwife must:

        a. Be currently certified as a nurse-midwife by the American College of Nurse-Midwives;

        b. Have satisfactorily completed a formal education program (of at least one academic year) that, upon completion, qualifies the nurse

to take the certification examination offered by the American College of Nurse-Midwives; or

c. Have successfully completed a formal education program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and have practiced as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976, to July 16, 1982.

C. Covered Services

1. General - Effective January 1, 1988, through December 31, 1993, the coverage of nurse-midwife services was restricted to the maternity cycle. The maternity cycle is a period that includes pregnancy, labor, and the immediate postpartum period.

Beginning with services furnished on or after January 1, 1994, coverage is no longer limited to the maternity cycle. Coverage is available for services furnished by a nurse-midwife that he or she is legally authorized to perform in the State in which the services are furnished and that would otherwise be covered if furnished by a physician, including obstetrical and gynecological services.

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2. Incident To - Services and supplies furnished incident to a nurse midwife's service are covered if they would have been covered when furnished incident to the services of a doctor of medicine or osteopathy, as described in §60.

D. Noncovered Services

The services of nurse-midwives are not covered if they are otherwise excluded from Medicare coverage even though a nurse-midwife is authorized by State law to perform them. For example, the Medicare program excludes from coverage routine physical checkups and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.

Coverage of service to the newborn continues only to the point that the newborn is or would normally be treated medically as a separate individual. Items and services furnished the newborn from that point are not covered on the basis of the mother's eligibility.

E. Relationship With Physician

Most States have licensure and other requirements applicable to nurse-midwives. For example, some require that the nurse-midwife have an arrangement with a physician for the referral of the patient in the event a problem develops that requires medical attention. Others may require that the nurse-midwife function under the general supervision of a

physician. Although these and similar State requirements must be met in order for the nurse-midwife to provide Medicare covered care, they have no effect on the nurse-midwife's right to personally bill for and receive direct Medicare payment. That is, billing does not have to flow through a physician or facility.

See §60.2 for coverage of services performed by nurse-midwives incident to the service of physicians.

F. Place of Service

There is no restriction on place of service. Therefore, nurse-midwife services are covered if provided in the nurse-midwife's office, in the patient's home, or in a hospital or other facility, such as a clinic or birthing center owned or operated by a nurse-midwife.

G. Assignment Requirement

Assignment is required.

190 - Physician Assistant (PA) Services

(Rev. 1, 10-01-03)
B3-2156

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No 11-35254 archived on August 3, 2012

Effective for services rendered on or after January 1, 1998, any individual who is participating under the Medicare program as a physician assistant for the first time may have his or her professional services covered if he or she meets the qualifications listed below and he or she is legally authorized to furnish PA services in the State where the services are performed. PAs who were issued billing provider numbers prior to January 1, 1998 may continue to furnish services under the PA benefit.

See the Medicare Claims Processing Manual, Chapter 12, "Physician and Nonphysician Practitioners," §110, for payment methodology for PA services. Payment is made under assignment only.

A. Qualifications for PAs

To furnish covered PA services, the PA must meet the conditions as follows:

1. Have graduated from a physician assistant educational program that is accredited by the Accreditation Review Commission on Education for the Physician Assistant (its predecessor agencies, the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the Committee on Allied Health Education and Accreditation (CAHEA); or

2. Have passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants (NCCPA); and

3. Be licensed by the State to practice as a physician assistant.

B. Covered Services

Coverage is limited to the services a PA is legally authorized to perform in accordance with State law (or State regulatory mechanism provided by State law).

1. General

The services of a PA may be covered under Part B, if all of the following requirements are met:

- They are the type that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO);
- They are performed by a person who meets all the PA qualifications,
- They are performed under the general supervision of an MD/DO;
- The PA is legally authorized to perform the services in the state in which they are performed; and
- They are not otherwise precluded from coverage because of one of the statutory exclusions.

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2. Incident To

If covered PA services are furnished, services and supplies furnished incident to the PA's services may also be covered if they would have been covered when furnished incident to the services of an MD/DO, as described in §60.

3. Types of PA Services That May Be Covered

State law or regulation governing a PA's scope of practice in the State in which the services are performed applies. Carriers should consider developing lists of covered services. Also, if authorized under the scope of their State license, PAs may furnish services billed under all levels of CPT evaluation and management codes, and diagnostic tests if furnished under the general supervision of a physician.

Examples of the types of services that PAs may provide include services that traditionally have been reserved to physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition.

See §60.2 for coverage of services performed by PAs incident to the services of physicians.

4. Services Otherwise Excluded From Coverage

The PA services may not be covered if they are otherwise excluded from coverage even though a PA may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care, routine physical checkups, and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Therefore, these services are precluded from coverage even though they may be within a PA's scope of practice under State law.

C. Physician Supervision

The PA's physician supervisor (or a physician designated by the supervising physician or employer as provided under State law or regulations) is primarily responsible for the overall direction and management of the PA's professional activities and for assuring that the services provided are medically appropriate for the patient. The physician supervisor (or physician designee) need not be physically present with the PA when a service is being furnished to a patient and may be contacted by telephone, if necessary, unless State law or regulations require otherwise.

D. Employment Relationship

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Payment for the services of a PA may be made only to the actual qualified employer of the PA that is eligible to enroll in the Medicare program under existing Medicare provider/supplier categories. If the employer of the PA is a professional corporation or other duly qualified legal entity (such as a limited liability company or a limited liability partnership), properly formed, authorized and licensed under State laws and regulations, that permits PA ownership in such corporation nor entity as a stockholder or member, that corporation or entity as the employer may bill for PA services even if a PA is a stockholder or officer of the entity, as long as the entity is entitled to enroll as a "provider of services" or a supplier of services in the Medicare program. Physician Assistants may not otherwise organize or incorporate and bill for their services directly to the Medicare program, including as, but not limited to sole proprietorships or general partnerships. Accordingly, a qualified employer is not a group of PAs that incorporate to bill for their services. Leasing agencies and staffing companies do not qualify under the Medicare program as "providers of services" or suppliers of services.

200 - Nurse Practitioner (NP) Services

(Rev. 75, Issued: 08-17-07, Effective: 11-19-07, Implementation: 11-19-07)

Effective for services rendered after January 1, 1998, any individual who is participating under the Medicare program as a nurse practitioner (NP) for the first time ever, may have his or her professional services covered if he or she meets the qualifications listed below, and he or she is legally authorized to furnish NP services in the State where the services

are performed. NPs who were issued billing provider numbers prior to January 1, 1998, may continue to furnish services under the NP benefit.

Payment for NP services is effective on the date of service, that is, on or after January 1, 1998, and payment is made on an assignment-related basis only.

A. Qualifications for NPs

In order to furnish covered NP services, an NP must meet the conditions as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; or

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner by December 31, 2000.

The following organizations are recognized national certifying bodies for NPs at the advanced practice level:

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- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

The NPs applying for a Medicare billing number for the first time on or after January 1, 2001, must meet the requirements as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and

- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

The NPs applying for a Medicare billing number for the first time on or after January 1, 2003, must meet the requirements as follows:

- Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law;

- Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; and

- Possess a master's degree in nursing.

B. Covered Services

Coverage is limited to the services an NP is legally authorized to perform in accordance with State law (or State regulatory mechanism established by State law).

1. General

The services of an NP may be covered under Part B if all of the following conditions are met:

- They are the type that are considered physician's services if furnished by a doctor of medicine or osteopathy (MD/DO);

- They are performed by a person who meets the definition of an NP (see subsection A);

- The NP is legally authorized to perform the services in the State in which they are performed;

- They are performed in collaboration with an MD/DO (see subsection D); and

- They are not otherwise precluded from coverage because of one of the statutory exclusions. (See subsection C.2.)

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2. Incident To

If covered NP services are furnished, services and supplies furnished incident to the services of the NP may also be covered if they would have been covered when furnished incident to the services of an MD/DO as described in §60.

C. Application of Coverage Rules

1. Types of NP Services That May Be Covered

State law or regulation governing an NP's scope of practice in the State in which the services are performed applies. Consider developing a list of covered services based on the State scope of practice. Examples of the types of services that NP's may furnish include services that traditionally have been reserved to physicians, such as physical

examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. Also, if authorized under the scope of their State license, NPs may furnish services billed under all levels of evaluation and management codes and diagnostic tests if furnished in collaboration with a physician.

See §60.2 for coverage of services performed by NPs incident to the services of physicians.

2. Services Otherwise Excluded From Coverage

The NP services may not be covered if they are otherwise excluded from coverage even though an NP may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care, routine physical checkups, and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Therefore, these services are precluded from coverage even though they may be within an NP's scope of practice under State law.

D. Collaboration

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Collaboration is a process in which an NP works with one or more physicians (MD/DO) to deliver health care services, with medical direction and appropriate supervision as required by the law of the State in which the services are furnished. In the absence of State law governing collaboration, collaboration is to be evidenced by NPs documenting their scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice.

The collaborating physician does not need to be present with the NP when the services are furnished or to make an independent evaluation of each patient who is seen by the NP.

E. Direct Billing and Payment

Direct billing and payment for NP services may be made to the NP.

F. Assignment

Assignment is mandatory.

210 - Clinical Nurse Specialist (CNS) Services

(Rev. 75, Issued: 08-17-07, Effective: 11-19-07, Implementation: 11-19-07)

Effective for services rendered after January 1, 1998, any individual who is participating under the Medicare program as a clinical nurse specialist (CNS) for the first time ever, may have his or her professional services covered if he or she meets the qualifications

listed below and he or she is legally authorized to furnish CNS services in the State where the services are performed. CNSs who were issued billing provider numbers prior to January 1, 1998, may continue to furnish services under the CNS benefit.

Payment for CNS services is effective on the date of service, that is, on or after January 1, 1998, and payment is made on an assignment-related basis only.

A. Qualifications for CNSs

In order to furnish covered CNS services, a CNS must meet the conditions as follows:

1. Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to furnish the services of a clinical nurse specialist in accordance with State law;

2. Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and

3. Be certified as a clinical nurse specialist by a recognized national certifying body that has established standards for CNSs.

The following organizations are recognized national certifying bodies for CNSs at the advanced practice level:

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- American Academy of Nurse Practitioners;
- American Nurses Credentialing Center;
- National Certification Corporation for Obstetric, Gynecologic and Neonatal Nursing Specialties;
- Pediatric Nursing Certification Board (previously named the National Certification Board of Pediatric Nurse Practitioners and Nurses);
- Oncology Nurses Certification Corporation;
- AACN Certification Corporation; and
- National Board on Certification of Hospice and Palliative Nurses.

B. Covered Services

Coverage is limited to the services a CNS is legally authorized to perform in accordance with State law (or State regulatory mechanism provided by State law).

1. General

The services of a CNS may be covered under Part B if all of the following conditions are met:

- They are the types of services that are considered as physician's services if furnished by an MD/DO;

- They are furnished by a person who meets the CNS qualifications (see subsection A);

- The CNS is legally authorized to furnish the services in the State in which they are performed;

- They are furnished in collaboration with an MD/DO as required by State law (see subsection C); and

- They are not otherwise excluded from coverage because of one of the statutory exclusions. (See subsection C.)

2. Types of CNS Services that May be Covered

State law or regulations governing a CNS' scope of practice in the State in which the services are furnished applies. Carriers must develop a list of covered services based on the State scope of practice.

Examples of the types of services that a CNS may furnish include services that traditionally have been reserved for physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. Also, if authorized under the scope of his or her State license, a CNS may furnish services billed under all levels of evaluation and management codes and diagnostic tests if furnished in collaboration with a physician.

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3. Incident To

If covered CNS services are furnished, services and supplies furnished incident to the services of the CNS may also be covered if they would have been covered when furnished incident to the services of an MD/DO as described in §60.

C. Application of Coverage Rules

1. Types of CNS Services

Examples of the types of services that CNS may provide are services that traditionally have been reserved for physicians, such as physical examinations, minor surgery, setting casts for simple fractures, interpreting x-rays, and other activities that involve an independent evaluation or treatment of the patient's condition. State law or regulation governing a CNS' scope of practice for his or her service area applies.

2. Services Otherwise Excluded From Coverage

A CNS' services are not covered if they are otherwise excluded from coverage even though a CNS may be authorized by State law to perform them. For example, the Medicare law excludes from coverage routine foot care and routine physical checkups and services that are not reasonable and necessary for diagnosis or treatment of an illness or injury or to improve the function of a malformed body member. Therefore, these services are precluded from coverage even though they may be within a CNS' scope of practice under State law.

See §60.2 for coverage of services performed by a CNS incident to the services of physicians.

D. Collaboration

Collaboration is a process in which a CNS works with one or more physicians (MD/DO) to deliver health care services within the scope of the CNS' professional expertise with medical direction and appropriate supervision as required by the law of the State in which the services are furnished. In the absence of State law governing collaboration, collaboration is to be evidenced by the CNS documenting his or her scope of practice and indicating the relationships that the CNS has with physicians to deal with issues outside the CNS' scope of practice.

The collaborating physician does not need to be present with the CNS when the services are furnished or to make an independent evaluation of each patient who is seen by the CNS.

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E. Direct Billing and Payment

A CNS may bill directly and receive direct payment for their services.

F. Assignment Requirement

Assignment is required for the service to be covered.

220 - Coverage of Outpatient Rehabilitation Therapy Services (Physical Therapy, Occupational Therapy, and Speech-Language Pathology Services) Under Medical Insurance

(Rev. 88, Issued: 05-07-08, Effective: 01-01-08, Implementation: 06-09-08)

A comprehensive knowledge of the policies that apply to therapy services cannot be obtained through manuals alone. The most definitive policies are Local Coverage Determinations found at the Medicare Coverage Database www.cms.hhs.gov/mcd. A list of Medicare contractors is found at the CMS Web site. Specific questions about all Medicare policies should be addressed to the contractors through the contact information

supplied on their Web sites. General Medicare questions may be addressed to the Medicare regional offices http://www.cms.hhs.gov/RegionalOffices/.

A. Definitions

The following defines terms used in this section and §230:

ACTIVE PARTICIPATION of the clinician in treatment means that the clinician personally furnishes in its entirety at least 1 billable service on at least 1 day of treatment.

ASSESSMENT is separate from evaluation, and is included in services or procedures, (it is not separately payable). The term assessment as used in Medicare manuals related to therapy services is distinguished from language in Current Procedural Terminology (CPT) codes that specify assessment, e.g., 97755, Assistive Technology Assessment, which may be payable). Assessments shall be provided only by clinicians, because assessment requires professional skill to gather data by observation and patient inquiry and may include limited objective testing and measurement to make clinical judgments regarding the patient's condition(s). Assessment determines, e.g., changes in the patient's status since the last visit/treatment day and whether the planned procedure or service should be modified. Based on these assessment data, the professional may make judgments about progress toward goals and/or determine that a more complete evaluation or re-evaluation (see definitions below) is indicated. Routine weekly assessments of expected progression in accordance with the plan are not payable as re-evaluations.

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CERTIFICATION is the physician's/nonphysician practitioner's (NPP) approval of the plan of care. Certification requires a dated signature on the plan of care or some other document that indicates approval of the plan of care.

The CLINICIAN is a term used in this manual and in Pub 100-04, chapter 5, section 10 or section 20, to refer to only a physician, nonphysician practitioner or a therapist (but not to an assistant, aide or any other personnel) providing a service within their scope of practice and consistent with state and local law. Clinicians make clinical judgments and are responsible for all services they are permitted to supervise. Services that require the skills of a therapist, may be appropriately furnished by clinicians, that is, by or under the supervision of qualified physicians/NPPs when their scope of practice, state and local laws allow it and their personal professional training is judged by Medicare contractors as sufficient to provide to the beneficiary skills equivalent to a therapist for that service.

COMPLEXITIES are complicating factors that may influence treatment, e.g., they may influence the type, frequency, intensity and/or duration of treatment. Complexities may be represented by diagnoses (ICD-9 codes), by patient factors such as age, severity, acuity, multiple conditions, and motivation, or by the patient's social circumstances such as the support of a significant other or the availability of transportation to therapy.

A DATE may be in any form (written, stamped or electronic). The date may be added to the record in any manner and at any time, as long as the dates are accurate. If they are

different, refer to both the date a service was performed and the date the entry to the record was made. For example, if a physician certifies a plan and fails to date it, staff may add "Received Date" in writing or with a stamp. The received date is valid for certification/re-certification purposes. Also, if the physician faxes the referral, certification, or re-certification and forgets to date it, the date that prints out on the fax is valid. If services provided on one date are documented on another date, both dates should be documented.

The EPISODE of Outpatient Therapy – For the purposes of therapy policy, an outpatient therapy episode is defined as the period of time, in calendar days, from the first day the patient is under the care of the clinician (e.g., for evaluation or treatment) for the current condition(s) being treated by one therapy discipline (PT, or OT, or SLP) until the last date of service for that discipline in that setting.

During the episode, the beneficiary may be treated for more than one condition; including conditions with an onset after the episode has begun. For example, a beneficiary receiving PT for a hip fracture who, after the initial treatment session, develops low back pain would also be treated under a PT plan of care for rehabilitation of low back pain. That plan may be modified from the initial plan, or it may be a separate plan specific to the low back pain, but treatment for both conditions concurrently would be considered the same episode of PT treatment. If that same patient developed a swallowing problem during intubation for the hip surgery, the first day of treatment by the SLP would be a new episode of SLP care.

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EVALUATION is a separately payable comprehensive service provided by a clinician, as defined above, that requires professional skills to make clinical judgments about conditions for which services are indicated based on objective measurements and subjective evaluations of patient performance and functional abilities. Evaluation is warranted e.g., for a new diagnosis or when a condition is treated in a new setting. These evaluative judgments are essential to development of the plan of care, including goals and the selection of interventions.

RE-EVALUATION provides additional objective information not included in other documentation. Re-evaluation is separately payable and is periodically indicated during an episode of care when the professional assessment of a clinician indicates a significant improvement, or decline, or change in the patient's condition or functional status that was not anticipated in the plan of care. Although some state regulations and state practice acts require re-evaluation at specific times, for Medicare payment, reevaluations must also meet Medicare coverage guidelines. The decision to provide a reevaluation shall be made by a clinician.

INTERVAL of certified treatment (certification interval) consists of 90 calendar days or less, based on an individual's needs. A physician/NPP may certify a plan of care for an interval length that is less than 90 days. There may be more than one certification interval in an episode of care. The certification interval is not the same as a Progress Report period.

NONPHYSICIAN PRACTITIONERS (NPP) means physician assistants, clinical nurse specialists, and nurse practitioners, who may, if state and local laws permit it, and when appropriate rules are followed, provide, certify or supervise therapy services.

PHYSICIAN with respect to outpatient rehabilitation therapy services means a doctor of medicine, osteopathy (including an osteopathic practitioner), podiatric medicine, or optometry (for low vision rehabilitation only). Chiropractors and doctors of dental surgery or dental medicine are not considered physicians for therapy services and may neither refer patients for rehabilitation therapy services nor establish therapy plans of care.

PATIENT, client, resident, and beneficiary are terms used interchangeably to indicate enrolled recipients of Medicare covered services.

PROVIDERS of services are defined in §1861(u) of the Act, 42CFR400.202 and 42CFR485 Subpart H as participating hospitals, critical access hospitals (CAH), skilled nursing facilities (SNF), comprehensive outpatient rehabilitation facilities (CORF), home health agencies (HHA), hospices, participating clinics, rehabilitation agencies or outpatient rehabilitation facilities (ORF). Providers are also defined as public health agencies with agreements only to furnish outpatient therapy services, or community mental health centers with agreements only to furnish partial hospitalization services. To qualify as providers of services, these providers must meet certain conditions enumerated in the law and enter into an agreement with the Secretary in which they agree not to charge any beneficiary for covered services for which the program will pay and to refund any erroneous collections made. Note that the word PROVIDER in sections 220 and 230 is not used to mean a person who provides a service, but is used as in the statute to mean a facility or agency such as rehabilitation agency or home health agency.

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QUALIFIED PROFESSIONAL means a physical therapist, occupational therapist, speech-language pathologist, physician, nurse practitioner, clinical nurse specialist, or physician's assistant, who is licensed or certified by the state to perform therapy services, and who also may appropriately perform therapy services under Medicare policies. Qualified professionals may also include physical therapist assistants (PTA) and occupational therapy assistants (OTA) when working under the supervision of a qualified therapist, within the scope of practice allowed by state law. Assistants are limited in the services they may provide (see section 230.1 and 230.2) and may not supervise others.

QUALIFIED PERSONNEL means staff (auxiliary personnel) who have been educated and trained as therapists and qualify to furnish therapy services only under direct supervision incident to a physician or NPP. See §230.5 of this manual. Qualified personnel may or may not be licensed as therapists but meet all of the requirements for therapists with the exception of licensure.

SIGNATURE means a legible identifier of any type acceptable according to policies in Pub. 100-08, Medicare Program Integrity Manual, chapter 3, §3.4.1.1 (B) concerning signatures.

SUPERVISION LEVELS for outpatient rehabilitation therapy services are the same as those for diagnostic tests defined in 42CFR410.32. Depending on the setting, the levels include personal supervision (in the room), direct supervision (in the office suite), and general supervision (physician/NPP is available but not necessarily on the premises).

SUPPLIERS of therapy services include individual practitioners such as physicians, NPPs, physical therapists and occupational therapists who have Medicare provider numbers. Regulatory references on physical therapists in private practice (PTPPs) and occupational therapists in private practice (OTPPs) are at 42CFR410.60 (C)(1), 485.701-729, and 486.150-163. Speech-language pathologists are not suppliers because the Act does not provide coverage of any speech-language pathology services furnished by a speech-language pathologist as an independent practitioner. (See §230.3.)

THERAPIST refers only to qualified physical therapists, occupational therapists and speech-language pathologists, as defined in §230. Qualifications that define therapists are in §§230.1, 230.2, and 230.3. Skills of a therapist are defined by the scope of practice for therapists in the state).

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THERAPY (or outpatient rehabilitation services) includes only outpatient physical therapy, occupational therapy and speech-language pathology services paid using the Medicare Physician Fee Schedule or the same services when provided in hospitals that are exempt from the hospital Outpatient Prospective Payment System and paid on a reasonable cost basis, including critical access hospitals.

Therapy services referred to in this manual are those skilled rehabilitative services provided according to the standards and conditions in CMS manuals, (e.g., in this chapter and in Pub. 100-04, Medicare Claims Processing Manual, chapter 5), within their scope of practice by qualified professionals or qualified personnel, as defined in this section, represented by procedures found in the American Medical Association's "Current Procedural Terminology (CPT)." A list of CPT (HCPCS) codes is provided in Pub. 100-04, chapter 5, §20, and in Local Coverage Determinations developed by contractors.

Unless modified by the words "maintenance" or "not", the term therapy refers to rehabilitative therapy services as described in §220.2(C).

TREATMENT DAY means a single calendar day on which treatment, evaluation and/or reevaluation is provided. There could be multiple visits, treatment sessions/encounters on a treatment day.

VISITS OR TREATMENT SESSIONS begin at the time the patient enters the treatment area (of a building, office, or clinic) and continue until all services (e.g., activities, procedures, services) have been completed for that session and the patient leaves that area

to participate in a non-therapy activity. It is likely that not all minutes in the visits/treatment sessions are billable (e.g., rest periods). There may be two treatment sessions in a day, for example, in the morning and afternoon. When there are two visits/ treatment sessions in a day, plans of care indicate treatment amount of twice a day.

B. References

Paper Manuals. The following manuals, now outdated, were resources for the Internet Only Manuals:

- Part A Medicare Intermediary Manual, (Pub. 13)
- Part B Medicare Carrier Manual, (Pub. 14)
- Hospital Manual, (Pub. 10)
- Outpatient Physical Therapy/CORF Manual, (Pub. 9)

Regulation and Statute. The information in this section is based in part on the following current references:
- 42CFR refers to Title 42, Code of Federal Regulation (CFR).
- The Act refers to the Social Security Act.

Internet Only Manuals. Current Policies that concern providers and suppliers of therapy services are located in many places throughout CMS Manuals. Sites that may be of interest include:

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- Pub.100-01 GENERAL INFORMATION, ELIGIBILITY, AND ENTITLEMENT,

  o Chapter 1- General Overview

    10.1 - Hospital Insurance (Part A) for Inpatient Hospital, Hospice and SNF Services - A Brief Description
    10.2 - Posthospital Home Health Services
    10.3 - Supplementary Medical Insurance (Part B) - A Brief Description
    20.2 - Discrimination Prohibited

- Pub. 100-02, MEDICARE BENEFIT POLICY MANUAL

  o Ch 6 - Hospital Services Covered Under Part B
    10 - Medical and Other Health Services Furnished to Inpatients of Participating Hospitals
    20 - Outpatient Hospital Services
    20.2 - Distinguishing Outpatient Hospital Services Provided Outside the Hospital
    20.4.1 - Coverage of Outpatient Therapeutic Services
    70 - Outpatient Hospital Psychiatric Services

  o Ch 8 - Coverage of Extended Care (SNF) Services Under Hospital

Insurance

30.4. - Direct Skilled Rehabilitation Services to Patients
40 - Physician Certification and Recertification
50.3 - Physical, Speech, and Occupational Therapy Furnished by the Skilled Nursing Facility or by Others Under Arrangements with the Facility and Under Its Supervision
70.3 - Inpatient Physical Therapy, Occupational Therapy, and Speech Pathology Services

• Pub. 100-03 MEDICARE NATIONAL COVERAGE DETERMINATIONS MANUAL

o Part 1

20.10 - Cardiac Rehabilitation Programs
30.1 - Biofeedback Therapy
30.1.1 - Biofeedback Therapy for the Treatment of Urinary Incontinence
50.1 – Speech Generating Devices
50.2 - Electronic Speech Aids
50.4 - Tracheostomy Speaking Valve

o Part 2

150.2 - Osteogenic Stimulator
150.4 - Neuromuscular Electrical Stimulator (NMES) in the Treatment of Disuse Atrophy
160.3 - Assessing Patient's Suitability for Electrical Nerve Stimulation
160.7 - Electrical Nerve Stimulators
160.11 - Osteogenic Stimulation
160.12 - Neuromuscular Electrical Stimulation (NMES)
160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)
160.17 - L-Dopa

o Part 3

170.1 - Institutional and Home Care Patient Education Programs
170.2 - Melodic Intonation Therapy
170.3 - Speech Pathology Services for the Treatment of Dysphagia
180 – Nutrition

o Part 4

230.8 - Non-implantable Pelvic Flood Electrical Stimulator
240.7 - Postural Drainage Procedures and Pulmonary Exercises

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270.1 -Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds
270.4 - Treatment of Decubitus Ulcers
280.3 - Specially Sized Wheelchairs
280.4 - Seat Lift
280.5 - Safety Roller
280.9 - Power Operated Vehicles That May Be Used as Wheelchairs
280.13 - Transcutaneous Electrical Nerve Stimulators (TENS)
290.1 - Home Health Visits to A Blind Diabetic

• Pub. 100-08 PROGRAM INTEGRITY MANUAL

o Chapter 3 - Verifying Potential Errors and Taking Corrective Actions
3.4.1.1 - Documentation Specifications for Areas Selected for Prepayment or Postpayment MR 3.4.1.1.1 Exception From the Uniform Dollar Limitation ("Therapy Cap")
o Chapter 13 - Local Coverage Determinations 13.5.1 - Reasonable and Necessary Provisions in LCDs Specific Therapy Policies**.** Sections 220 and 230 of this chapter describe the standards and conditions that apply generally to outpatient rehabilitation therapy services.

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Specific policies may differ by setting. Other policies concerning therapy services are found in other manuals. When a therapy service policy is specific to a setting, it takes precedence over these general outpatient policies. For special rules on:

• CORFs - See chapter 12 of this manual and also Pub. 100-04, chapter 5;
• SNF - See chapter 8 of this manual and also Pub. 100-04, chapter 6, for SNF claims/billing;
• HHA - See chapter 7 of this manual, and Pub. 100-04, chapter 10;
• GROUP THERAPY AND STUDENTS - See Pub. 100-02, chapter 15, §230;
• ARRANGEMENTS - Pub. 100-01, chapter 5, §10.3;
• COVERAGE is described in the Medicare Program Integrity Manual, Pub. 100-08, chapter 13, §13.5.1; and
• THERAPY CAPS - See Pub. 100-04, chapter 5, §10.2, for a complete description of this financial limitation.

C. General

Therapy services are a covered benefit in §§1861(g), 1861(p), and 1861(ll) of the Act. Therapy services may also be provided incident to the services of a physician/NPP under §§1861(s)(2) and 1862(a)(20) of the Act.

Covered therapy services are furnished by providers, by others under arrangements with and under the supervision of providers, or furnished by suppliers (e.g., physicians, NPP, enrolled therapists), who meet the requirements in Medicare manuals for therapy services.

Where a prospective payment system (PPS) applies, therapy services are paid when services conform to the requirements of that PPS. For example, see Pub. 100-04 for a description of applicable Inpatient Hospital Part B and Outpatient PPS rules. Reimbursement for therapy provided to Part A inpatients of hospitals or residents of SNFs in covered stays is included in the respective PPS rates.

Payment for therapy provided by an HHA under a plan of treatment is included in the home health PPS rate. Therapy may be billed by an HHA on bill type 34x if there are no home health services billed under a home health plan of care at the same time (e.g., the patient is not homebound), and there is a valid therapy plan of treatment.

In addition to the requirements described in this chapter, the services must be furnished in accordance with health and safety requirements set forth in regulations at 42CFR484, and 42CFR485.

When therapy services may be furnished appropriately in a community pool by a clinician in a physical therapist or occupational therapist private practice, physician office, outpatient hospital, or outpatient SNF, the practice/office or provider shall rent or lease the pool, or a specific portion of the pool. The use of that part of the pool during specified times shall be restricted to the patients of that practice or provider. The written agreement to rent or lease the pool shall be available for review on request. When part of the pool is rented or leased, the agreement shall describe the part of the pool that is used exclusively by the patients of that practice/office or provider and the times that exclusive use applies. Other providers, including providers of outpatient physical therapy and speech-language pathology (OPTs or rehabilitation agencies) and CORFs, are subject to the requirements outlined in the respective State Operations Manual regarding rented or leased community pools.

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220.1 - Conditions of Coverage and Payment for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

Reference: 42CFR424.24

Refer to §230.4 for physical therapist/occupational therapist in private practice rules.

Coverage rules for specific services are in Pub. 100-03, the Medicare National Coverage Determinations Manual.

Other payment rules are found in Pub. 100-04, chapter 5.

Since the outpatient therapy benefit under Part B provides coverage only of therapy services, payment can be made only for those services that constitute therapy. In cases

where there is doubt about whether a service is therapy, the contractor's local coverage determination (LCD) shall prevail.

In order for a service to be covered, it must have a benefit category in the statute, it must not be excluded and it must be reasonable and necessary. Therapy services are a benefit under §1861 of the Act. Consult Pub. 100-08, chapter 13, §13.5.1 for full descriptions of a reasonable and necessary service.

Outpatient therapy services furnished to a beneficiary by a provider or supplier are payable only when furnished in accordance with certain conditions. The following conditions of coverage apply. The requirements noted (*) are also conditions of payment in 42CFR424.24(c) and according to the Act §1835 (a)(2)(D) are the three conditions that must be certified:

- (i) such services are or were required because the individual needed therapy services* (see §220.1.3); and
- (ii) a plan for furnishing such services has been established by a physician/NPP or by the therapist providing such services and is periodically reviewed by a physician/NPP* (see §220.1.2); and
- (iii) such services are or were furnished while the individual is or was under the care of a physician* (see §220.1.1); and
- Services must be furnished on an outpatient basis. (See §220.1.4)
- All of the conditions are met when a physician/NPP certifies an outpatient plan of care for therapy. Certification is required for coverage and payment of a therapy claim. Each of these conditions is discussed separately in the sections that follow.

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220.1.1 - Outpatient Therapy Must be Under the Care of a Physician/Nonphysician Practitioners (NPP) (Orders/Referrals and Need for Care)

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

An order (sometimes called a referral) for therapy service, if it is documented in the medical record, provides evidence of both the need for care and that the patient is under the care of a physician. However, the certification requirements are met when the physician certifies the plan of care. If the signed order includes a plan of care (see essential requirements of plan in §220.1.2), no further certification of the plan is required. Payment is dependent on the certification of the plan of care rather than the order, but the use of an order is prudent to determine that a physician is involved in care and available to certify the plan.

(The CORF services benefit does not recognize an NPP for orders and certification.)

220.1.2 - Plans of Care for Outpatient Physical Therapy, Occupational Therapy, or Speech-Language Pathology Services

(Rev. 88, Issued: 05-07-08, Effective: 01-01-08, Implementation: 06-09-08)

Reference: 42CFR 410.61

A. Establishing the plan (See §220.1.3 for certifying the plan.)

The services must relate directly and specifically to a written treatment plan as described in this chapter. The plan, (also known as a plan of care or plan of treatment) must be established before treatment is begun. The plan is established when it is developed (e.g., written or dictated).

The signature and professional identity (e.g., MD, OTR/L) of the person who established the plan, and the date it was established must be recorded with the plan. Establishing the plan, which is described below, is not the same as certifying the plan, which is described in §§220.1.1 and 220.1.3

Outpatient therapy services shall be furnished under a plan established by:

- A physician/NPP (consultation with the treating physical therapist, occupational therapist, or speech-language pathologist is recommended. Only a physician may establish a plan of care in a CORF);
- The physical therapist who will provide the physical therapy services;
- The occupational therapist who will provide the occupational therapy services; or
- The speech-language pathologist who will provide the speech-language pathology services.

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The plan may be entered into the patient's therapy record either by the person who established the plan or by the provider's or supplier's staff when they make a written record of that person's oral orders before treatment is begun.

Treatment under a Plan. The evaluation and treatment may occur and are both billable either on the same day or at subsequent visits. It is appropriate that treatment begins when a plan is established.

Therapy may be initiated by qualified professionals or qualified personnel based on a dictated plan. Treatment may begin before the plan is committed to writing only if the treatment is performed or supervised by the same clinician who establishes the plan. Payment for services provided before a plan is established may be denied.

Two Plans. It is acceptable to treat under two separate plans of care when different physician's/NPP's refer a patient for different conditions. It is also acceptable to combine the plans of care into one plan covering both conditions if one or the other referring physician/NPP is willing to certify the plan for both conditions. The Treatment Notes continue to require timed code treatment minutes and total treatment time and need not be separated by plan. Progress Reports should be combined if it is possible to make clear that the goals for each plan are addressed. Separate Progress Reports referencing each plan of care may also be written, at the discretion of the treating clinician, or at the request of the certifying physician/NPP, but shall not be required by contractors.

B. Contents of Plan (See §220.1.3 for certifying the plan.)

The plan of care shall contain, at minimum, the following information as required by regulation (42CFR424.24 and 410.61) (See §220.3 for further documentation requirements):

- Diagnoses;
- Long term treatment goals; and
- Type, amount, duration and frequency of therapy services.

The plan of care shall be consistent with the related evaluation, which may be attached and is considered incorporated into the plan. The plan should strive to provide treatment in the most efficient and effective manner, balancing the best achievable outcome with the appropriate resources.

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Long term treatment goals should be developed for the entire episode of care in the current setting. When the episode is anticipated to be long enough to require more than one certification, the long term goals may be specific to the part of the episode that is being certified. Goals should be measurable and pertain to identified functional impairments. When episodes in the setting are short, measurable goals may not be achievable; documentation should state the clinical reasons progress cannot be shown.

The type of treatment may be PT, OT, or SLP, or, where appropriate, the type may be a description of a specific treatment or intervention. (For example, where there is a single evaluation service, but the type is not specified, the type is assumed to be consistent with the therapy discipline (PT, OT, SLP) ordered, or of the therapist who provided the evaluation.) Where a physician/NPP establishes a plan, the plan must specify the type (PT, OT, SLP) of therapy planned.

There shall be different plans of care for each type of therapy discipline. When more than one discipline is treating a patient, each must establish a diagnosis, goals, etc. independently. However, the form of the plan and the number of plans incorporated into one document are not limited as long as the required information is present and related to each discipline separately. For example, a physical therapist may not provide services

under an occupational therapist plan of care. However, both may be treating the patient for the same condition at different times in the same day for goals consistent with their own scope of practice.

The amount of treatment refers to the number of times in a day the type of treatment will be provided. Where amount is not specified, one treatment session a day is assumed.

The frequency refers to the number of times in a week the type of treatment is provided. Where frequency is not specified, one treatment is assumed. If a scheduled holiday occurs on a treatment day that is part of the plan, it is appropriate to omit that treatment day unless the clinician who is responsible for writing Progress Reports determines that a brief, temporary pause in the delivery of therapy services would adversely affect the patient's condition.

The duration is the number of weeks, or the number of treatment sessions, for THIS PLAN of care. If the episode of care is anticipated to extend beyond the 90 calendar day limit for certification of a plan, it is desirable, although not required, that the clinician also estimate the duration of the entire episode of care in this setting.

The frequency or duration of the treatment may not be used alone to determine medical necessity, but they should be considered with other factors such as condition, progress, and treatment type to provide the most effective and efficient means to achieve the patients' goals. For example, it may be clinically appropriate, medically necessary, most efficient and effective to provide short term intensive treatment or longer term and less frequent treatment depending on the individuals' needs.

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It may be appropriate for therapists to taper the frequency of visits as the patient progresses toward an independent or caregiver assisted self management program with the intent of improving outcomes and limiting treatment time. For example, treatment may be provided 3 times a week for 2 weeks, then 2 times a week for the next 2 weeks, then once a week for the last 2 weeks. Depending on the individual's condition, such treatment may result in better outcomes, or may result in earlier discharge than routine treatment 3 times a week for 4 weeks. When tapered frequency is planned, the exact number of treatments per frequency level is not required to be projected in the plan, because the changes should be made based on assessment of daily progress. Instead, the beginning and end frequencies shall be planned. For example, amount, frequency and duration may be documented as "once daily, 3 times a week tapered to once a week over 6 weeks". Changes to the frequency may be made based on the clinicians clinical judgment and do not require recertification of the plan unless requested by the physician/NPP. The clinician should consider any comorbidities, tissue healing, the ability of the patient **and/or caregiver to do more independent self management** as treatment progresses, and any other factors related to frequency and duration of treatment.

The above policy describes the minimum requirements for payment. It is anticipated that clinicians may choose to make their plans more specific, in accordance with good

practice. For example, they may include these optional elements: short term goals, goals and duration for the current episode of care, specific treatment interventions, procedures, modalities or techniques and the amount of each. Also, notations in the medical record of beginning date for the plan are recommended but not required to assist Medicare contractors in determining the dates of services for which the plan was effective.

C. Changes to the Therapy Plan

Changes are made in writing in the patient's record and signed by one of the following professionals responsible for the patient's care:

- The physician/NPP;
- The physical therapist (in the case of physical therapy);
- The speech-language pathologist (in the case of speech-language pathology services);
- The occupational therapist (in the case of occupational therapy services; or
- The registered professional nurse or physician/NPP on the staff of the facility pursuant to the oral orders of the physician/NPP or therapist.

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While the physician/NPP may change a plan of treatment established by the therapist providing such services, the therapist may not significantly alter a plan of treatment established or certified by a physician/NPP without their documented written or verbal approval [See §220.1.3(C)]. A change in long-term goals, (for example if a new condition was to be treated) would be a significant change. Physician/NPP certification of the significantly modified plan of care shall be obtained within 30 days of the initial therapy treatment under the revised plan. An insignificant alteration in the plan would be a change in the frequency or duration due to the patient's illness, or a modification of short-term goals to adjust for improvements made toward the same long-term goals. If a patient has achieved a goal and/or has had no response to a treatment that is part of the plan, the therapist may delete a specific intervention from the plan of care prior to physician/ NPP approval. This shall be reported to the physician/NPP responsible for the patient's treatment prior to the next certification.

Procedures (e.g., neuromuscular reeducation) and modalities (e.g., ultrasound) are not goals, but are the means by which long and short term goals are obtained. Changes to procedures and modalities do not require physician signature when they represent adjustments to the plan that result from a normal progression in the patient's disease or condition or adjustments to the plan due to lack of expected response to the planned intervention, when the goals remain unchanged. Only when the patient's condition changes significantly, making revision of long term goals necessary, is a physician's/NPP's signature required on the change, (long term goal changes may be accompanied by changes to procedures and modalities).

220.1.3 - Certification and Recertification of Need for Treatment and Therapy Plans of Care

(Rev. 88, Issued: 05-07-08, Effective: 01-01-08, Implementation: 06-09-08)

Reference: 42CFR424.24(c)

See specific certification rules in Pub. 100-01, chapter 4, §20 for hospital services.

A. Method and Disposition of Certifications

Certification requires a dated signature on the plan of care or some other document that indicates approval of the plan of care. It is not appropriate for a physician/NPP to certify a plan of care if the patient was not under the care of some physician/NPP at the time of the treatment or if the patient did not need the treatment. Since delayed certification is allowed, the date the certification is signed is important only to determine if it is timely or delayed. The certification must relate to treatment during the interval on the claim. Unless there is reason to believe the plan was not signed appropriately, or it is not timely, no further evidence that the patient was under the care of a physician/NPP and that the patient needed the care is required.

The format of all certifications and recertifications and the method by which they are obtained is determined by the individual facility and/or practitioner. Acceptable documentation of certification may be, for example, a physician's progress note, a physician/NPP order, or a plan of care that is signed and dated by a physician/NPP, and indicates the physician/NPP is aware that therapy service is or was in progress and the physician/NPP makes no record of disagreement with the plan when there is evidence the plan was sent (e.g., to the office) or is available in the record (e.g., of the institution that employs the physician/NPP) for the physician/NPP to review. For example, if during the course of treatment under a certified plan of care a physician sends an order for continued treatment for 2 more weeks, contractors shall accept the order as certification of continued treatment for 2 weeks under the same plan of care. If the new certification is for less treatment than previously planned and certified, this new certification takes the place of any previous certification. At the end of the 2 weeks of treatment (which might extend more than 2 calendar weeks from the date the order/certification was signed) another certification would be required if further treatment was documented as medically necessary.

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The certification should be retained in the clinical record and available if requested by the contractor.

B. Initial Certification of Plan

The physician's/NPP's certification of the plan (with or without an order) satisfies all of the certification requirements noted above in §220.1 for the duration of the plan of care, or 90 calendar days from the date of the initial treatment, whichever is less. The initial treatment includes the evaluation that resulted in the plan.

Timing of Initial Certification. The provider or supplier (e.g., facility, physician/NPP, or therapist) should obtain certification as soon as possible after the plan of care is established, unless the requirements of delayed certification are met. "As soon as possible" means that the physician/NPP shall certify the initial plan as soon as it is obtained, or within 30 days of the initial therapy treatment. Since payment may be denied if a physician does not certify the plan, the therapist should forward the plan to the physician as soon as it is established. Evidence of diligence in providing the plan to the physician may be considered by the Medicare contractor during review in the event of a delayed certification.

Timely certification of the initial plan is met when physician/NPP certification of the plan is documented, by signature or verbal order, and dated in the 30 days following the first day of treatment (including evaluation). If the order to certify is verbal, it must be followed within 14 days by a signature to be timely. A dated notation of the order to certify the plan should be made in the patient's medical record.

Recertification is not required if the duration of the initially certified plan of care is more than the duration (length) of the entire episode of treatment.

C. Review of Plan and Recertification

Reference: 42CFR424.24(c), 1861(r), 42CFR 410.61(e).

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The timing of recertification changed on January 1, 2008. Certifications signed on or after January 1, 2008, follow the rules in this section. Certifications signed on or prior to December 31, 2007, follow the rule in effect at that time, which required recertification every 30 calendar days.

Payment and coverage conditions require that the plan must be reviewed, as often as necessary but at least whenever it is certified or recertified to complete the certification requirements. It is not required that the same physician/NPP who participated initially in recommending or planning the patient's care certify and/or recertify the plans.

Recertifications that document the need for continued or modified therapy should be signed whenever the need for a significant modification of the plan becomes evident, or at least every 90 days after initiation of treatment under that plan, unless they are delayed.

Physician/NPP Options for Certification. A physician/NPP may certify or recertify a plan for whatever duration of treatment the physician/NPP determines is appropriate, up to a maximum of 90 calendar days. Many episodes of therapy treatment last less than 30 calendar days. Therefore, it is expected that the physician/NPP should certify a plan that appropriately estimates the duration of care for the individual, even if it is less than 90 days. If the therapist writes a plan of care for a duration that is more or less than the duration approved by the physician/NPP, then the physician/NPP would document a change to the duration of the plan and certify it for the duration the physician/NPP finds appropriate (up to 90 days). Treatment beyond the duration certified by the

physician/NPP requires that a plan be recertified for the extended duration of treatment. It is possible that patients will be discharged by the therapist before the end of the estimated treatment duration because some will improve faster than estimated and/or some were successfully progressed to an independent home program.

Physicians/NPPs may require that the patient make a physician/NPP visit for an examination if, in the professional's judgment, the visit is needed prior to certifying the plan, or during the planned treatment. Physicians/NPPs should indicate their requirement for visits, preferably on an order preceding the treatment, or on the plan of care that is certified. If the physician wishes to restrict the patient's treatment beyond a certain date when a visit is required, the physician should certify a plan only until the date of the visit. After that date, services will not be considered reasonable and necessary due to lack of a certified plan. Physicians/NPPs should not sign a certification if they require a visit and a visit was not made. However, Medicare does not require a visit unless the National Coverage Determination (NCD) for a particular treatment requires it (e.g., see Pub. 100-03, §270.1 - Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds).

Restrictions on Certification. Certifications and recertifications by doctors of podiatric medicine must be consistent with the scope of the professional services provided by a doctor of podiatric medicine as authorized by applicable state law. Optometrists may order and certify only low vision services. Chiropractors may not certify or recertify plans of care for therapy services.

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D. Delayed Certification

References: §1835(a) of the Act
42CFR424.11(d)(3)

Certifications are required for each interval of treatment based on the patient's needs, not to exceed 90 calendar days from the initial therapy treatment. Certifications are timely when the initial certification (or certification of a significantly modified plan of care) is dated within 30 calendar days of the initial treatment under that plan. Recertification is timely when dated during the duration of the initial plan of care or within 90 calendar days of the initial treatment under that plan, whichever is less. Delayed certification and recertification requirements shall be deemed satisfied where, at any later date, a physician/NPP makes a certification accompanied by a reason for the delay. Certifications are acceptable without justification for 30 days after they are due. Delayed certification should include one or more certifications or recertifications on a single signed and dated document.

Delayed certifications should include any evidence the provider or supplier considers necessary to justify the delay. For example, a certification may be delayed because the physician did not sign it, or the original was lost. In the case of a long delayed certification (over 6 months), the provider or supplier may choose to submit with the delayed certification some other documentation (e.g., an order, progress notes, telephone

contact, requests for certification or signed statement of a physician/NPP) indicating need for care and that the patient was under the care of a physician at the time of the treatment. Such documentation may be requested by the contractor for delayed certifications if it is required for review.

It is not intended that needed therapy be stopped or denied when certification is delayed. The delayed certification of otherwise covered services should be accepted unless the contractor has reason to believe that there was no physician involved in the patient's care, or treatment did not meet the patient's need (and therefore, the certification was signed inappropriately).

EXAMPLE: Payment should be denied if there is a certification signed 2 years after treatment by a physician/NPP who has/had no knowledge of the patient when the medical record also shows e.g., no order, note, physician/NPP attended meeting, correspondence with a physician/NPP, documentation of discussion of the plan with a physician/NPP, documentation of sending the plan to any physician/NPP, or other indication that there was a physician/NPP involved in the case.

EXAMPLE: Payment should not be denied, even when certified 2 years after treatment, when there is evidence that a physician approved needed treatment, such as an order, documentation of therapist/physician/NPP discussion of the plan, chart notes, meeting notes, requests for certification, certifications for intervals before or after the service in question, or physician/NPP services during which the medical record or the patient's history would, in good practice, be reviewed and would indicate therapy treatment is in progress.

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EXAMPLE: Subsequent certifications of plans for continued treatment for the same condition in the same patient may indicate physician certification of treatment that occurred between certification dates, even if the signature for one of the plans in the episode is delayed. If a certified plan of care ends March 30th and a new plan of care for continued treatment after March 30th is developed or signed by a therapist on April 15th and that plan is subsequently certified, that certification may be considered delayed and acceptable effective from the first treatment date after March 30th for the frequency and duration as described in the plan. Of course, documentation should continue to indicate that therapy during the delay is medically necessary, as it would for any treatment. The certification of the physician/NPP is interpreted as involvement and approval of the ongoing episode of treatment, including the treatment that preceded the date of the certification unless the physician/NPP indicates otherwise.

E. Denials Due to Certification

Denial for payment that is based on absence of certification is a technical denial, which means a statutory requirement has not been met. Certification is a statutory requirement in SSA 1835(a)(2)- ('periodic review" of the plan).

For example, if a patient is treated and the provider/supplier cannot produce (on contractor request) a plan of care (timely or delayed) for the billed treatment dates certified by a physician/NPP, then that service might be denied for lack of the required certification. If an appropriate certification is later produced, the denial shall be overturned.

In the case of a service furnished under a provider agreement as described in 42CFR489.21, the provider is precluded from charging the beneficiary for services denied as a result of missing certification.

However, if the service is provided by a supplier (in the office of the physician/NPP, or therapist) a technical denial due to absence of a certification results in beneficiary liability. For that reason, it is recommended that the patient be made aware of the need for certification and the consequences of its absence.

A technical denial decision may be reopened by the contractor or reversed on appeal as appropriate, if delayed certification is later produced.

220.1.4 - Requirement That Services Be Furnished on an Outpatient Basis

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

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Reference: 42CFR410.60

Therapy services are payable under the Physician Fee Schedule when furnished by 1.) a provider to its outpatients in the patient's home; 2.) a provider to patients who come to the facility's outpatient department; 3.) a provider to inpatients of other institutions, or 4.) a supplier to patients in the office or in the patient's home. (CORF rules differ on providing therapy at home.)

Coverage includes therapy services furnished by participating hospitals and SNFs to their inpatients who have exhausted Part A inpatient benefits or who are otherwise not eligible for Part A benefits. Providers of therapy services that have inpatient facilities, other than participating hospitals and SNFs, may not furnish covered therapy services to their own inpatients. However, since the inpatients of one institution may be considered the outpatients of another institution, all providers of therapy services may furnish such services to inpatients of another health facility.

A certified distinct part of an institution is considered to be a separate institution from a nonparticipating part of the institution. Consequently, the certified distinct part may render covered therapy services to the inpatients of the noncertified part of the institution or to outpatients. The certified part must bill the intermediary under Part B.

Therapy services are payable when furnished in the home at the same physician fee schedule payments as in other outpatient settings. Additional expenses incurred by providers due to travel to a person who is not homebound will not be covered.

Under the Medicare law, there is no authority to require a provider to furnish a type of service. Therefore, a hospital or SNF may furnish therapy to its inpatients without having to set up facilities and procedures for furnishing those services to its outpatients. However, if the provider chooses to furnish a particular service, it may not charge any individual or other person for items or services for which the individual is entitled to have payment made under the program because it is bound by its agreement with Medicare. Thus, whenever a hospital or SNF furnishes outpatient therapy to a Medicare beneficiary (either directly or under arrangements with others) it must bill the program under Part B and may charge the patient only for the applicable deductible and coinsurance.

220.2 - Reasonable and Necessary Outpatient Rehabilitation Therapy Services

(Rev. 63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

References: Pub. 100-08, chapter 13, §13.5.1,
42CFR410.59,
42CFR410.60

A. General

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To be covered, services must be skilled therapy services as described in this chapter and be rendered under the conditions specified. Services provided by professionals or personnel who do not meet the qualification standards, and services by qualified people that are not appropriate to the setting or conditions are unskilled services. Unskilled services are palliative procedures that are repetitive or reinforce previously learned skills, or maintain function after a maintenance program has been developed.

Services which do not meet the requirements for covered therapy services in Medicare manuals are not payable using codes and descriptions for therapy services. For example, services related to activities for the general good and welfare of patients, e.g., general exercises to promote overall fitness and flexibility and activities to provide diversion or general motivation, do not constitute therapy services for Medicare purposes. Also, services not provided under a therapy plan of care, or are provided by staff who are not qualified or appropriately supervised, are not covered or payable therapy services.

Examples of coverage policies that apply to all outpatient therapy claims are in this chapter, in Pub. 100-04, chapter 5, and Pub. 100-08, chapter 13. Some policies in other manuals are repeated here for emphasis and clarification. Further details on documenting reasonable and necessary services are found in section 220.3 of this chapter.

B. Reasonable and Necessary

To be considered reasonable and necessary the following conditions must each be met. (This is a representative list of required conditions and does not fully describe reasonable

and necessary services. See the remainder of this section and associated information in section 230.):

- The services shall be considered under accepted standards of medical practice to be a specific and effective treatment for the patient's condition. Acceptable practices for therapy services are found in:

  - Medicare manuals (such as this manual and Publications 100-03 and 100-04),

  - Contractors Local Coverage Determinations (LCDs and NCDs are available on the Medicare Coverage Database: http://www.cms.hhs.gov/mcd, and

  - Guidelines and literature of the professions of physical therapy, occupational therapy and speech-language pathology.

- The services shall be of such a level of complexity and sophistication or the condition of the patient shall be such that the services required can be safely and effectively performed only by a therapist, or in the case of physical therapy and occupational therapy by or under the supervision of a therapist. Services that do not require the performance or supervision of a therapist are not skilled and are not considered reasonable or necessary therapy services, even if they are performed or supervised by a qualified professional.

- If the contractor determines the services furnished were of a type that could have been safely and effectively performed only by or under the supervision of such a qualified professional, it shall presume that such services were properly supervised when required. However, this presumption is rebuttable, and, if in the course of processing claims it finds that services are not being furnished under proper supervision, it shall deny the claim and bring this matter to the attention of the Division of Survey and Certification of the Regional Office.

- While a beneficiary's particular medical condition is a valid factor in deciding if skilled therapy services are needed, a beneficiary's diagnosis or prognosis should never be the sole factor in deciding that a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury, or whether the services can be carried out by nonskilled personnel. See item C for descriptions of skilled (rehabilitative) services.

- There must be an expectation that the patient's condition will improve significantly in a reasonable (and generally predictable) period of time, or the services must be necessary for the establishment of a safe and effective maintenance program required in connection with a specific disease state. In the case of a progressive degenerative disease, service may be intermittently necessary to determine the need for assistive equipment and/or establish a program to maximize function (see item D for descriptions of maintenance services); and

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- The amount, frequency, and duration of the services must be reasonable under accepted standards of practice. The contractor shall consult local professionals or the state or national therapy associations in the development of any utilization guidelines.

NOTE: Claims for therapy services denied because they are not considered reasonable and necessary are excluded by §1862(a)(1) of the Act and are thus subject to consideration under the waiver of liability provision in §1879 of the Act.

C. Rehabilitative Therapy

Description of Rehabilitative Therapy. The concept of rehabilitative therapy includes recovery or improvement in function and, when possible, restoration to a previous level of health and well-being. Therefore, evaluation, re-evaluation and assessment documented in the Progress Report should describe objective measurements which, when compared, show improvements in function, or decrease in severity, or rationalization for an optimistic outlook to justify continued treatment.

Covered therapy services shall be rehabilitative therapy services unless they meet the criteria for maintenance therapy requiring the skills of a therapist described below. Rehabilitative therapy services are skilled procedures that may include but are not limited to:

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Evaluations; reevaluations.

Establishment of treatment goals specific to the patient's disability or dysfunction and designed to specifically address each problem identified in the evaluation;

Design of a plan of care addressing the patient's disorder, including establishment of procedures to obtain goals, determining the frequency and intensity of treatment;

Continued assessment and analysis during implementation of the services at regular intervals;

Instruction leading to establishment of compensatory skills;

Selection of devices to replace or augment a function (e.g., for use as an alternative communication system and short-term training on use of the device or system); and

Patient and family training to augment rehabilitative treatment or establish a maintenance program. Education of staff and family should be ongoing

through treatment and instructions may have to be modified intermittently if the patient's status changes.

Skilled Therapy. Rehabilitative therapy occurs when the skills of a therapist, (See definition of therapist in section 220 of this chapter) are necessary to safely and effectively furnish a recognized therapy service whose goal is improvement of an impairment or functional limitation. (See also section 220.3 of this chapter for documenting skilled therapy.)

Skilled therapy may be needed, and improvement in a patient's condition may occur, even where a chronic or terminal condition exists. For example, a terminally ill patient may begin to exhibit self-care, mobility, and/or safety dependence requiring skilled therapy services. The fact that full or partial recovery is not possible does not necessarily mean that skilled therapy is not needed to improve the patient's condition. In the case of a progressive degenerative disease, for example, service may be intermittently necessary to determine the need for assistive equipment and establish a program to maximize function. The deciding factors are always whether the services are considered reasonable, effective treatments for the patient's condition and require the skills of a therapist, or whether they can be safely and effectively carried out by nonskilled personnel without the supervision of qualified professionals.

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Services that can be safely and effectively furnished by nonskilled personnel or by PTAs or OTAs without the supervision of therapists are not rehabilitative therapy services. If at any point in the treatment of an illness it is determined that the treatment is not rehabilitative, or does not legitimately require the services of a qualified professional for management of a maintenance program as described below, the services will no longer be considered reasonable and necessary. Services that are not reasonable or necessary should be excluded from coverage under §1862(a)(1) of the Act.

Potential for Improvement Due to Treatment. If an individual's expected rehabilitation potential would be insignificant in relation to the extent and duration of physical therapy services required to achieve such potential, therapy would not be covered because it is not considered rehabilitative or reasonable and necessary.

Improvement is evidenced by successive objective measurements whenever possible (see objective measurement instruments for evaluation in the §220.3.C of this chapter).

Therapy is not required to effect improvement or restoration of function where a patient suffers a transient and easily reversible loss or reduction of function (e.g., temporary weakness which may follow a brief period of bed rest following abdominal surgery) which could reasonably be expected to improve spontaneously as the patient gradually resumes normal activities. Therapy furnished in such situations is not considered reasonable and necessary for the treatment of the individual's illness or injury and the services are not covered. (See exceptions for maintenance in §220.2D of this manual).

D. Maintenance Programs

During the last visits for rehabilitative treatment, the clinician may develop a maintenance program. The goals of a maintenance program would be, for example, to maintain functional status or to prevent decline in function. The specialized skill, knowledge and judgment of a therapist would be required, and services are covered, to design or establish the plan, assure patient safety, train the patient, family members and/or unskilled personnel and make infrequent but periodic reevaluations of the plan.

The services of a qualified professional are not necessary to carry out a maintenance program, and are not covered under ordinary circumstances. The patient may perform such a program independently or with the assistance of unskilled personnel or family members.

Where a maintenance program is not established until after the rehabilitative therapy program has been completed (and the skills of a therapist are not necessary) development of a maintenance program would not be considered reasonable and necessary for the treatment of the patient's condition. It would be excluded from coverage under §1862(a)(1) of the Act unless the patient's safety was at risk (see below).

EXAMPLE: A Parkinson patient who has been under a rehabilitative physical therapy program may require the services of a therapist during the last week or two of treatment to determine what type of exercises will contribute the most to maintain the patient's present functional level following cessation of treatment. In such situations, the design of a maintenance program appropriate to the capacity and tolerance of the patient by the qualified therapist, the instruction of the patient or family members in carrying out the program, and such infrequent reevaluations as may be required would constitute covered therapy because of the need for the skills of a qualified professional.

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<u>Evaluation and Maintenance Plan without Rehabilitative Treatment.</u> After the initial evaluation of the extent of the disorder, illness, or injury, if the treating qualified professional determines the potential for rehabilitation is insignificant, an appropriate maintenance program may be established prior to discharge. Since the skills of a therapist are required for the development of the maintenance program and training the patient or caregivers, this service is covered.

EXAMPLE: The skills of a qualified speech-language pathologist may be covered to develop a maintenance program for a patient with multiple sclerosis, for services intended to prevent or minimize deterioration in communication ability caused by the medical condition, when the patient's current medical condition does not yet justify the need for the skilled services of a speech-language pathologist. Evaluation, development of the program and training the family or support personnel would require the skills of a therapist and would be covered. The skills of a therapist are not required and services are not covered to carry out the program.

<u>Skilled Maintenance Therapy for Safety.</u> If the services required to maintain function involve the use of complex and sophisticated therapy procedures, the judgment and skill

of a therapist may be necessary for the safe and effective delivery of such services. When the patient's safety is at risk, those reasonable and necessary services shall be covered, even if the skills of a therapist are not ordinarily needed to carry out the activities performed as part of the maintenance program.

Example. Where there is an unhealed, unstable fracture, which requires regular exercise to maintain function until the fracture heals, the skills of a therapist would be needed to ensure that the fractured extremity is maintained in proper position and alignment during maintenance range of motion exercises.

220.3 - Documentation Requirements for Therapy Services

(Rev. 88, Issued: 05-07-08, Effective: 01-01-08, Implementation: 06-09-08)

A. General

Therapy services shall be payable when the medical record and the information on the claim form consistently and accurately report covered therapy services. Documentation must be legible, relevant and sufficient to justify the services billed. In general, services must be covered therapy services provided according to the requirements in Medicare manuals. Medicare requires that the services billed be supported by documentation that justifies payment. Documentation must comply with all legal/regulatory requirements applicable to Medicare claims.

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The documentation guidelines in sections 220 and 230 of this chapter identify the minimal expectations of documentation by providers or suppliers or beneficiaries submitting claims for payment of therapy services to the Medicare program. State or local laws and policies, or the policies of the profession, the practice, or the facility may be more stringent. Additional documentation not required by Medicare is encouraged when it conforms to state or local law or to professional guidelines of the American Physical Therapy Association, the American Occupational Therapy Association, or the American Speech-Language Hearing Association. It is encouraged but not required that narratives that specifically justify the medical necessity of services be included in order to support approval when those services are reviewed. (See also section 220.2-Reasonable and Necessary Outpatient Rehabilitation Therapy Services)

Contractors shall consider the entire record when reviewing claims for medical necessity so that the absence of an individual item of documentation does not negate the medical necessity of a service when the documentation as a whole indicates the service is necessary. Services are medically necessary if the documentation indicates they meet the requirements for medical necessity including that they are skilled, rehabilitative services, provided by clinicians (or qualified professionals when appropriate) with the approval of a physician/NPP, safe, and effective (i.e., progress indicates that the care is effective in rehabilitation of function).

B. Documentation Required

List of required documentation. These types of documentation of therapy services are expected to be submitted in response to any requests for documentation, unless the contractor requests otherwise. The timelines are minimum requirements for Medicare payment. Document as often as the clinician's judgment dictates but no less than the frequency required in Medicare policy:

- Evaluation /and Plan of Care (may be one or two documents). Include the initial evaluation and any re-evaluations relevant to the episode being reviewed;

- Certification (physician/NPP approval of the plan) and recertifications when records are requested after the certification/recertification is due. See definitions in section 220 and certification policy in section 220.1.3 of this chapter. Certification (and recertification of the plan when applicable) are required for payment and must be submitted when records are requested after the certification or recertification is due.

- Progress Reports (including Discharge Notes, if applicable) when records are requested after the reports are due. (See definitions in section 220 and descriptions in 220.3 D);

- Treatment Notes for each treatment day (may also serve as Progress Reports when required information is included in the notes); and

- A separate justification statement may be included either as a separate document or within the other documents if the provider/supplier wishes to assure the contractor understands their reasoning for services that are more extensive than is typical for the condition treated. A separate statement is not required if the record justifies treatment without further explanation.

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Limits on Requirements. Contractors shall not require more specific documentation unless other Medicare manual policies require it. Contractors may request further information to be included in these documents concerning specific cases under review when that information is relevant, but not submitted with records.

Dictated Documentation. For Medicare purposes, dictated therapy documentation is considered completed on the day it was dictated. The qualified professional may edit and electronically sign the documentation at a later date.

Dates for Documentation. The date the documentation was made is important only to establish the date of the initial plan of care because therapy cannot begin until the plan is established unless treatment is performed or supervised by the same clinician who establishes the plan. However, contractors may require that treatment notes and progress reports be entered into the record within 1 week of the last date to which the Progress Report or Treatment Note refers. For example, if treatment began on the first of the month at a frequency of twice a week, a Progress Report would be required at the end of the month. Contractors may require that the Progress Report that describes that month of

treatment be dated not more than 1 week after the end of the month described in the report.

Document Information to Meet Requirements. In documenting records, clinicians must be familiar with the requirements for covered and payable outpatient therapy services as described in the manuals. For example, the records should justify:

- The patient is under the care of a physician/NPP;

  Physician/NPP care shall be documented by physician/NPP certification (approval) of the plan of care; and

  Although not required, other evidence of physician/NPP involvement in the patient's care may include, for example: order/referral, conference, team meeting notes, and correspondence.

- Services require the skills of a therapist.

  Services must not only be provided by the qualified professional or qualified personnel, but they must require, for example, the expertise, knowledge, clinical judgment, decision making and abilities of a therapist that assistants, qualified personnel, caretakers or the patient cannot provide independently. A clinician may not merely supervise, but must apply the skills of a therapist by actively participating in the treatment of the patient during each Progress Report Period. In addition, a therapist's skills may be documented, for example, by the clinician's descriptions of their skilled treatment, the changes made to the treatment due to a clinician's assessment of the patient's needs on a particular treatment day or changes due to progress the clinician judged sufficient to modify the treatment toward the next more complex or difficult task.

  A therapist's skill may also be required for safety reasons, if an unstable fracture requires the skill of a therapist to do an activity that might otherwise be done independently by the patient at home. Or the skill of a therapist might be required for a patient learning compensatory swallowing techniques to perform cervical auscultation and identify changes in voice and breathing that might signal aspiration. After the patient is judged safe for independent use of these compensatory techniques, the skill of a therapist is not required to feed the patient, or check what was consumed.

- Services are of appropriate type, frequency, intensity and duration for the individual needs of the patient.

  Documentation should establish the variables that influence the patient's condition, especially those factors that influence the clinician's decision to provide more services than are typical for the individual's condition.

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Clinicians and contractors shall determine typical services using published professional literature and professional guidelines. The fact that services are typically billed is not necessarily evidence that the services are typically appropriate. Services that exceed those typically billed should be carefully documented to justify their necessity, but are payable if the individual patient benefits from medically necessary services. Also, some services or episodes of treatment should be less than those typically billed, when the individual patient reaches goals sooner than is typical.

Documentation should establish through objective measurements that the patient is making progress toward goals. Note that regression and plateaus can happen during treatment. It is recommended that the reasons for lack of progress be noted and the justification for continued treatment be documented if treatment continues after regression or plateaus.

Needs of the Patient. When a service is reasonable and necessary, the patient also needs the services. Contractors determine the patient's needs through knowledge of the individual patient's condition, and any complexities that impact that condition, as described in documentation (usually in the evaluation, re-evaluation, and Progress Report). Factors that contribute to need vary, but in general they relate to such factors as the patient's diagnoses, complicating factors, age, severity, time since onset/acuity, self-efficacy/motivation, cognitive ability, prognosis, and/or medical, psychological and social stability. Patients who need therapy generally respond to therapy, so changes in objective and sometimes to subjective measures of improvement also help establish the need for services. The use of scientific evidence, obtained from professional literature, and sequential measurements of the patient's condition during treatment is encouraged to support the potential for continued improvement that may justify the patients need for therapy.

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C. Evaluation/Re-Evaluation and Plan of Care

The initial evaluation, or the plan of care including an evaluation, should document the necessity for a course of therapy through objective findings and subjective patient self-reporting. Utilize the guidelines of the American Physical Therapy Association, the American Occupational Therapy Association, or the American Speech-Language and Hearing Association as guidelines, and not as policy. Only a clinician may perform an initial examination, evaluation, re-evaluation and assessment or establish a diagnosis or a plan of care. A clinician may include, as part of the evaluation or re-evaluation, objective measurements or observations made by a PTA or OTA within their scope of practice, but the clinician must actively and personally participate in the evaluation or re-evaluation. The clinician may not merely summarize the objective findings of others or make judgments drawn from the measurements and/or observations of others.

Documentation of the evaluation should list the conditions and complexities and, where it is not obvious, describe the impact of the conditions and complexities on the prognosis and/or the plan for treatment such that it is clear to the contractor who may review the record that the services planned are appropriate for the individual.

Evaluation shall include:

- A diagnosis (where allowed by state and local law) and description of the specific problem(s) to be evaluated and/or treated. The diagnosis should be specific and as relevant to the problem to be treated as possible. In many cases, both a medical diagnosis (obtained from a physician/NPP) and an impairment based treatment diagnosis related to treatment are relevant. The treatment diagnosis may or may not be identified by the therapist, depending on their scope of practice. Where a diagnosis is not allowed, use a condition description similar to the appropriate ICD-9 code. For example the medical diagnosis made by the physician is CVA; however, the treatment diagnosis or condition description for PT may be abnormality of gait, for OT, it may be hemiparesis, and for SLP, it may be dysphagia. For PT and OT, be sure to include the body part evaluated. Include all conditions and complexities that may impact the treatment. A description might include, for example, the premorbid function, date of onset, and current function;

- **Results of one of the following four measurement instruments are recommended, but not required:**

  National Outcomes Measurement System (NOMS) by the American Speech-Language Hearing Association

  Patient Inquiry by Focus On Therapeutic Outcomes, Inc. (FOTO)

  Activity Measure – Post Acute Care (AM-PAC)

  OPTIMAL by Cedaron through the American Physical Therapy Association

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- If results of one of the four instruments above is not recorded, the record shall contain instead the following information indicated by asterisks (*) and should contain (but is not required to contain) all of the following, as applicable. Since published research supports its impact on the need for treatment, information in the following indented bullets may also be included with the results of the above four instruments in the evaluation report at the clinician's discretion. This information may be incorporated into a test instrument or separately reported within the required documentation. If it changes, update this information in the re-evaluation, and/or Treatment Notes, and/or Progress Reports, and/or in a separate record. When it is provided, contractors shall take this documented information into account to determine whether services are reasonable and necessary.

  Documentation supporting illness severity or complexity including, e.g.,

- Identification of other health services concurrently being provided for this condition (e.g., physician, PT, OT, SLP, chiropractic, nurse, respiratory therapy, social services, psychology, nutritional/dietetic services, radiation therapy, chemotherapy, etc.), and/ or

- Identification of durable medical equipment needed for this condition, and/or

- Identification of the number of medications the beneficiary is talking (and type if known); and/or

- If complicating factors (complexities) affect treatment, describe why or how. For example: Cardiac dysrhythmia is not a condition for which a therapist would directly treat a patient, but in some patients such dysrhythmias may so directly and significantly affect the pace of progress in treatment for other conditions as to require an exception to caps for necessary services. Documentation should indicate how the progress was affected by the complexity. Or, the severity of the patient's condition as reported on a functional measurement tool may be so great as to suggest extended treatment is anticipated; and/or

- Generalized or multiple conditions. The beneficiary has, in addition to the primary condition being treated, another disease or condition being treated, or generalized musculoskeletal conditions, or conditions affecting multiple sites and these conditions will directly and significantly impact the rate of recovery; and/or.

- Mental or cognitive disorder. The beneficiary has a mental or cognitive disorder in addition to the condition being treated that will directly and significantly impact the rate of recovery; and/or.

- Identification of factors that impact severity including e.g., age, time since onset, cause of the condition, stability of symptoms, how typical/atypical are the symptoms of the diagnosed condition, availability of an intervention/treatment known to be effective, predictability of progress.

Documentation supporting medical care prior to the current episode, if any, (or document none) including, e.g.,

- Record of discharge from a Part A qualifying inpatient, SNF, or home health episode within 30 days of the onset of this outpatient therapy episode, or

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- Identification of whether beneficiary was treated for this same condition previously by the same therapy discipline (regardless of where prior services were furnished; and

- Record of a previous episode of therapy treatment from the same or different therapy discipline in the past year.

Documentation required to indicate beneficiary health related to quality of life, specifically,

- The beneficiary's response to the following question of self-related health: "At the present time, would you say that your health is excellent, very good, fair, or poor?" If the beneficiary is unable to respond, indicate why; and

Documentation required to indicate beneficiary social support including, specifically,

- Where does the beneficiary live (or intend to live) at the conclusion of this outpatient therapy episode? (e.g., private home, private apartment, rented room, group home, board and care apartment, assisted living, SNF), and

- Who does beneficiary live with (or intend to live with) at the conclusion of this outpatient therapy episode? (e.g., lives alone, spouse/significant other, child/children, other relative, unrelated person(s), personal care attendant), and

- Does the beneficiary require this outpatient therapy plan of care in order to return to a premorbid (or reside in a new) living environment, and

- Does the beneficiary require this outpatient therapy plan of care in order to reduce Activities of Daily Living (ADL) or Instrumental Activities of Daily Living or (IADL) assistance to a premorbid level or to reside in a new level of living environment (document prior level of independence and current assistance needs); and

*Documentation required to indicate objective, measurable beneficiary physical function including, e.g.,

- Functional assessment individual item and summary scores (and comparisons to prior assessment scores) from commercially available therapy outcomes instruments other than those listed above; or

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- Functional assessment scores (and comparisons to prior assessment scores) from tests and measurements validated in the professional literature that are appropriate for the condition/function being measured; or

- Other measurable progress towards identified goals for functioning in the home environment at the conclusion of this therapy episode of care.

- Clinician's clinical judgments or subjective impressions that describe the current functional status of the condition being evaluated, when they provide further information to supplement measurement tools; and

- A determination that treatment is not needed, or, if treatment is needed a prognosis for return to premorbid condition or maximum expected condition with expected time frame and a plan of care.

NOTE: When the Evaluation Serves as the Plan of Care. When an evaluation is the only service provided by a provider/supplier in an episode of treatment, the evaluation serves as the plan of care if it contains a diagnosis, or in states where a therapist may not diagnose, a description of the condition from which a diagnosis may be determined by the referring physician/NPP. The goal, frequency, and duration of treatment are implied in the diagnosis and one-time service. The referral/order of a physician/NPP is the certification that the evaluation is needed and the patient is under the care of a physician. Therefore, when evaluation is the only service, a referral/order and evaluation are the only required documentation. If the patient presented for evaluation without a referral or order and does not require treatment, a physician referral/order or certification of the evaluation is required for payment of the evaluation. A referral/order dated after the evaluation shall be interpreted as certification of the plan to evaluate the patient.

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The time spent in evaluation shall not also be billed as treatment time. Evaluation minutes are untimed and are part of the total treatment minutes, but minutes of evaluation shall not be included in the minutes for timed codes reported in the treatment notes.

Re-evaluations shall be included in the documentation sent to contractors when a re-evaluation has been performed. See the definition in section 220. Re-evaluations are usually focused on the current treatment and might not be as extensive as initial evaluations. Continuous assessment of the patient's progress is a component of ongoing therapy services and is not payable as a re-evaluation. A re-evaluation is not a routine, recurring service but is focused on evaluation of progress toward current goals, making a professional judgment about continued care, modifying goals and/or treatment or terminating services. A formal re-evaluation is covered only if the documentation supports the need for further tests and measurements after the initial evaluation. Indications for a re-evaluation include new clinical findings, a significant change in the patient's condition, or failure to respond to the therapeutic interventions outlined in the plan of care.

A re-evaluation may be appropriate prior to planned discharge for the purposes of determining whether goals have been met, or for the use of the physician or the treatment setting at which treatment will be continued.

A re-evaluation is focused on evaluation of progress toward current goals and making a professional judgment about continued care, modifying goals and/or treatment or terminating services. Reevaluation requires the same professional skills as evaluation. The minutes for re-evaluation are documented in the same manner as the minutes for evaluation. Current Procedural Terminology does not define a re-evaluation code for speech-language pathology; use the evaluation code.

Plan of Care. See section 220.1.2 for requirements of the plan. The evaluation and plan may be reported in two separate documents or a single combined document.

D. Progress Report

The Progress Report provides justification for the medical necessity of treatment.

Contractors shall determine the necessity of services based on the delivery of services as directed in the plan and as documented in the Treatment Notes and Progress Report. For Medicare payment purposes, information required in Progress Reports shall be written by a clinician that is, either the physician/NPP who provides or supervises the services, or by the therapist who provides the services and supervises an assistant. It is not required that the referring or supervising physician/NPP sign the Progress Reports written by a PT, OT or SLP.

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Timing. The minimum Progress Report Period shall be at least once every 10 treatment days or at least once during each 30 calendar days, whichever is less. The day beginning the first reporting period is the first day of the episode of treatment regardless of whether the service provided on that day is an evaluation, re-evaluation or treatment. Regardless of the date on which the report is actually written (and dated), the end of the Progress Report Period is either a date chosen by the clinician, the 10th treatment day, or the 30th calendar day of the episode of treatment, whichever is shorter. The next treatment day begins the next reporting period. The Progress Report Period requirements are complete when both the elements of the Progress Report and the clinician's active participation in treatment have been documented.

For example, for a patient evaluated on Monday, October 1 and being treated five times a week, on weekdays: On October 5, (before it is required), the clinician may choose to write a Progress Report for the last week's treatment (from October 1 to October 5). October 5 ends the reporting period and the next treatment on Monday, October 8 begins the next reporting period. If the clinician does not choose to write a report for the next week, the next report is required to cover October 8 through October 19, which would be 10 treatment days.

It should be emphasized that the dates for recertification of plans of care do not affect the dates for required Progress Reports. (Consideration of the case in preparation for a report may lead the therapist to request early recertification. However, each report does not require recertification of the plan, and there may be several reports between recertifications). In many settings, weekly Progress Reports are voluntarily prepared to review progress, describe the skilled treatment, update goals, and inform physician/NPPs or other staff. The clinical judgment demonstrated in frequent reports may help justify that the skills of a therapist are being applied, and that services are medically necessary. Particularly where the patient's medical status, or appropriate tapering of frequency due to expected progress towards goals, results in limited frequency e.g., (2-4 times a month), more frequent Progress Reports can differentiate rehabilitative from maintenance treatment, document progress and justify the continued necessity for skilled care.

Absences. Holidays, sick days or other patient absences may fall within the Progress Report Period. Days on which a patient does not encounter qualified professional or qualified personnel for treatment, evaluation or re-evaluation do not count as treatment days. However, absences do not affect the requirement for a Progress Report at least once during each Progress Report Period. If the patient is absent unexpectedly at the end of the reporting period, when the clinician has not yet provided the required active participation during that reporting period, a Progress Report is still required, but without the clinician's active participation in treatment, the requirements of the Progress Report Period are incomplete.

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Delayed Reports. If the clinician has not written a Progress Report before the end of the Progress Reporting Period, it shall be written within 7calendar days after the end of the reporting period. If the clinician did not participate actively in treatment during the Progress Report Period, documentation of the delayed active participation shall be entered in the Treatment Note as soon as possible. The Treatment Note shall explain the reason for the clinician's missed active participation. Also, the Treatment Note shall document the clinician's guidance to the assistant or qualified personnel to justify that the skills of a therapist were required during the reporting period. It is not necessary to include in this Treatment Note any information already recorded in prior Treatment Notes or Progress Reports.

The contractor shall make a clinical judgment whether continued treatment by assistants or qualified personnel is reasonable and necessary when the clinician has not actively participated in treatment for longer than one reporting period. Judgment shall be based on the individual case and documentation of the application of the clinician's skills to guide the assistant or qualified personnel during and after the reporting period.

Early Reports. Often, Progress Reports are written weekly, or even daily, at the discretion of the clinician. Clinicians are encouraged, but not required to write Progress Reports more frequently than the minimum required in order to allow anyone who reviews the records to easily determine that the services provided are appropriate, covered and payable.

Elements of Progress Reports may be written in the Treatment Notes if the provider/supplier or clinician prefers. If each element required in a Progress Report is included in the Treatment Notes at least once during the Progress Report Period, then a separate Progress Report is not required. Also, elements of the Progress Report may be incorporated into a revised Plan of Care when one is indicated. Although the Progress Report written by a therapist does not require a physician/NPP signature when written as a stand-alone document, the revised Plan of Care accompanied by the Progress Report shall be re-certified by a physician/NPP. See the section 220.1.2C on Plan of Care for guidance on when a revised plan requires certification.

Progress Reports for Services Billed Incident to a Physician's Service. The policy for incident to services requires, for example, the physician's initial service, direct supervision of therapy services, and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment (See section 60.1B of this chapter. Also, see the billing requirements for services incident to a physician in Pub. 100-04, chapter 26, Items 17, 19, 24, and 31.) Therefore, supervision and reporting requirements for supervising physician/NPPs supervising staff are the same as those for PTs and OTs supervising PTAs and OTAs with certain exceptions noted below.

When a therapy service is provided by a therapist, supervised by a physician/NPP and billed incident to the services of the physician/NPP, the Progress Report shall be written and signed by the therapist who provides the services.

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When the services incident to a physician are provided by qualified personnel who are not therapists, the ordering or supervising physician/NPP must personally provide at least one treatment session during each Progress Report Period and sign the Progress Report.

Documenting Clinician Participation in Treatment in the Progress Report. Verification of the clinician's required participation in treatment during the Progress Report Period shall be documented by the clinician's signature on the Treatment Note and/or on the Progress Report. When unexpected discontinuation of treatment occurs, contractors shall not require a clinician's participation in treatment for the incomplete reporting period.

The Discharge Note (or Discharge Summary) is required for each episode of outpatient treatment. In provider settings where the physician/NPP writes a discharge summary and the discharge documentation meets the requirements of the provider setting, a separate discharge note written by a therapist is not required. The Discharge Note shall be a Progress Report written by a clinician, and shall cover the reporting period from the last Progress Report to the date of discharge. In the case of a discharge unanticipated in the plan or previous Progress Report, the clinician may base any judgments required to write the report on the Treatment Notes and verbal reports of the assistant or qualified personnel.

In the case of a discharge anticipated within 3 treatment days of the Progress Report, the clinician may provide objective goals which, when met, will authorize the assistant or

qualified personnel to discharge the patient. In that case, the clinician should verify that the services provided prior to discharge continued to require the skills of a therapist, and services were provided or supervised by a clinician. The Discharge Note shall include all treatment provided since the last Progress Report and indicate that the therapist reviewed the notes and agrees to the discharge.

At the discretion of the clinician, the discharge note may include additional information; for example, it may summarize the entire episode of treatment, or justify services that may have extended beyond those usually expected for the patient's condition. Clinicians should consider the discharge note the last opportunity to justify the medical necessity of the entire treatment episode in case the record is reviewed. The record should be reviewed and organized so that the required documentation is ready for presentation to the contractor if requested.

Assistant's Participation in the Progress Report Physical Therapist Assistants or Occupational Therapy Assistants may write elements of the Progress Report dated between clinician reports. Reports written by assistants are not complete Progress Reports. The clinician must write a Progress Report during each Progress Report Period regardless of whether the assistant writes other reports. However, reports written by assistants are part of the record and need not be copied into the clinicians report. Progress Reports written by assistants supplement the reports of clinicians and shall include:

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- Date of the beginning and end of the reporting period that this report refers to;

- Date that the report was written (not required to be within the reporting period);

- Signature, and professional identification, or for dictated documentation, the identification of the qualified professional who wrote the report and the date on which it was dictated;

- Objective reports of the patient's subjective statements, if they are relevant. For example, "Patient reports pain after 20 repetitions". Or, "The patient was not feeling well on 11/05/06 and refused to complete the treatment session."; and

- Objective measurements (preferred) or description of changes in status relative to each goal currently being addressed in treatment, if they occur. Note that assistants may not make clinical judgments about why progress was or was not made, but may report the progress objectively. For example: "increasing strength" is not an objective measurement, but "patient ambulates 15 feet with maximum assistance" is objective.

Descriptions shall make identifiable reference to the goals in the current plan of care. Since only long term goals are required in the plan of care, the Progress Report may be used to add, change or delete short term goals. Assistants may change goals only under the direction of a clinician. When short term goal changes are dictated to an assistant or to qualified personnel, report the change, clinician's name, and date. Clinicians verify

these changes by cosignatures on the report or in the clinician's Progress Report. (See section 220.1.2(C) to modify the plan for changes in long term goals).

The evaluation and plan of care are considered incorporated into the Progress Report, and information in them is not required to be repeated in the report. For example, if a time interval for the treatment is not specifically stated, it is assumed that the goals refer to the plan of care active for the current Progress Report Period. If a body part is not specifically noted, it is assumed the treatment is consistent with the evaluation and plan of care.

Any consistent method of identifying the goals may be used. Preferably, the long term goals may be numbered (1, 2, 3,) and the short term goals that relate to the long term goals may be numbered and lettered 1.A, 1.B, etc. The identifier of a goal on the plan of care may not be changed during the episode of care to which the plan refers. A clinician, an assistant on the order of a therapist or qualified personnel on the order of a physician/NPP shall add new goals with new identifiers or letters. Omit reference to a goal after a clinician has reported it to be met, and that clinician's signature verifies the change.

Content of Clinician (Therapist, Physician/NPP) Progress Reports. In addition to the requirements above for notes written by assistants, the Progress Report of a clinician shall also include:

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- Assessment of improvement, extent of progress (or lack thereof) toward each goal;

- Plans for continuing treatment, reference to additional evaluation results, and/or treatment plan revisions should be documented in the clinician's Progress Report; and

- Changes to long or short term goals, discharge or an updated plan of care that is sent to the physician/NPP for certification of the next interval of treatment.

A re-evaluation should not be required before every Progress Report routinely, but may be appropriate when assessment suggests changes not anticipated in the original plan of care.

Care must be taken to assure that documentation justifies the necessity of the services provided during the reporting period, particularly when reports are written at the minimum frequency. Justification for treatment must include, for example, objective evidence or a clinically supportable statement of expectation that:

- The patient's condition has the potential to improve or is improving in response to therapy;

- Maximum improvement is yet to be attained; and

- There is an expectation that the anticipated improvement is attainable in a reasonable and generally predictable period of time.

Objective evidence consists of standardized patient assessment instruments, outcome measurements tools or measurable assessments of functional outcome. Use of objective measures at the beginning of treatment, during and/or after treatment is recommended to quantify progress and support justifications for continued treatment. Such tools are not required, but their use will enhance the justification for needed therapy.

Example: The Plan states diagnosis is 787.2- Dysphagia secondary to other late effects of CVA. Patient is on a restricted diet and wants to drink thick liquids. Therapy is planned 3X week, 45 minute sessions for 6 weeks. Long term goal is to consume a mechanical soft diet with thin liquids without complications such as aspiration pneumonia. Short Term Goal 1: Patient will improve rate of laryngeal elevation/timing of closure by using the super-supraglottic swallow on saliva swallows without cues on 90% of trials. Goal 2: Patient will compensate for reduced laryngeal elevation by controlling bolus size to ½ teaspoon without cues 100%. The Progress Report for 1/3/06 to 1/29/06 states: 1. Improved to 80% of trials; 2. Achieved. Comments: Highly motivated; spouse assists with practicing, compliant with current restrictions. New Goal: "5. Patient will implement above strategies to swallow a sip of water without coughing for 5 consecutive trials. Mary Johns, CCC-SLP, 1/29/06." Note the provider is billing 92526 three times a week, consistent with the plan; progress is documented; skilled treatment is documented.

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E. Treatment Note

The purpose of these notes is simply to create a record of all treatments and skilled interventions that are provided and to record the time of the services in order to justify the use of billing codes on the claim. Documentation is required for every treatment day, and every therapy service. The format shall not be dictated by contractors and may vary depending on the practice of the responsible clinician and/or the clinical setting.

The Treatment Note is not required to document the medical necessity or appropriateness of the ongoing therapy services. Descriptions of skilled interventions should be included in the plan or the Progress Reports and are allowed, but not required daily. Non-skilled interventions need not be recorded in the Treatment Notes as they are not billable. However, notation of non-skilled treatment or report of activities performed by the patient or non-skilled staff may be reported voluntarily as additional information if they are relevant and not billed. Specifics such as number of repetitions of an exercise and other details included in the plan of care need not be repeated in the Treatment Notes unless they are changed from the plan.

Documentation of each Treatment shall include the following required elements:

- Date of treatment; and

- Identification of each specific intervention/modality provided and billed, for both timed and untimed codes, in language that can be compared with the billing on the claim to verify correct coding. Record each service provided that is represented by a timed code, regardless of whether or not it is billed, because the unbilled timed services may impact the billing; and

- Total timed code treatment minutes and total treatment time in minutes. Total treatment time includes the minutes for timed code treatment and untimed code treatment. Total treatment time does not include time for services that are not billable (e.g., rest periods). For Medicare purposes, it is not required that unbilled services that are not part of the total treatment minutes be recorded, although they may be included voluntarily to provide an accurate description of the treatment, show consistency with the plan, or comply with state or local policies. The amount of time for each specific intervention/modality provided to the patient may also be recorded voluntarily, but contractors shall not require it, as it is indicated in the billing. The billing and the total timed code treatment minutes must be consistent. See Pub. 100-04, chapter 5, section 20.2 for description of billing timed codes; and

- Signature and professional identification of the qualified professional who furnished or supervised the services and a list of each person who contributed to that treatment (i.e., the signature of Kathleen Smith, PTA, with notation of phone consultation with Judy Jones, PT, supervisor, when permitted by state and local law). The signature and identification of the supervisor need not be on each Treatment Note, unless the supervisor actively participated in the treatment. Since a clinician must be identified on the Plan of Care and the Progress Report, the name and professional identification of the supervisor responsible for the treatment is assumed to be the clinician who wrote the plan or report. When the treatment is supervised without active participation by the supervisor, the supervisor is not required to cosign the Treatment Note written by a qualified professional. When the responsible supervisor is absent, the presence of a similarly qualified supervisor on the clinic roster for that day is sufficient documentation and it is not required that the substitute supervisor sign or be identified in the documentation.

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If a treatment is added or changed under the direction of a clinician during the treatment days between the Progress Reports, the change must be recorded and justified on the medical record, either in the Treatment Note or the Progress Report, as determined by the policies of the provider/supplier. New exercises added or changes made to the exercise program help justify that the services are skilled. For example: The original plan was for therapeutic activities, gait training and neuromuscular re-education. "On Feb. 1 clinician added electrical stim. to address shoulder pain."

Documentation of each treatment may also include the following optional elements to be mentioned only if the qualified professional recording the note determines they are appropriate and relevant. If these are not recorded daily, any relevant information should be included in the progress report.

- Patient self-report;
- Adverse reaction to intervention;
- Communication/consultation with other providers (e.g., supervising clinician, attending physician, nurse, another therapist, etc.);
- Significant, unusual or unexpected changes in clinical status;
- Equipment provided; and/or
- Any additional relevant information the qualified professional finds appropriate.

See Pub. 100-04, chapter 5, section 20.2 for instructions on how to count minutes. It is important that the total number of timed treatment minutes support the billing of units on the claim, and that the total treatment time reflects services billed as untimed codes.

230 - Practice of Physical Therapy, Occupational Therapy, and Speech-Language Pathology

(Rev. 63, Issued: 12-29-06, Effective: 01-01-07, Implementation: on or before 01-29-07)

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A. Group Therapy Services. Contractors pay for outpatient physical therapy services (which includes outpatient speech-language pathology services) and outpatient occupational therapy services provided simultaneously to two or more individuals by a practitioner as group therapy services (97150). The individuals can be, but need not be performing the same activity. The physician or therapist involved in group therapy services must be in constant attendance, but one-on-one patient contact is not required.

B. Therapy Students

1. General

Only the services of the therapist can be billed and paid under Medicare Part B. The services performed by a student are not reimbursed even if provided under “line of sight” supervision of the therapist; however, the presence of the student “in the room” does not make the service unbillable. Pay for the direct (one-to-one) patient contact services of the physician or therapist provided to Medicare Part B patients. Group therapy services performed by a therapist or physician may be billed when a student is also present “in the room”.

EXAMPLES:

Therapists may bill and be paid for the provision of services in the following scenarios:

- The qualified practitioner is present and in the room for the entire session. The student participates in the delivery of services when the qualified practitioner is directing the service, making the skilled judgment, and is responsible for the assessment and treatment.

- The qualified practitioner is present in the room guiding the student in service delivery when the therapy student and the therapy assistant student are participating in the provision of services, and the practitioner is not engaged in treating another patient or doing other tasks at the same time.

- The qualified practitioner is responsible for the services and as such, signs all documentation. (A student may, of course, also sign but it is not necessary since the Part B payment is for the clinician's service, not for the student's services).

2. Therapy Assistants as Clinical Instructors

Physical therapist assistants and occupational therapy assistants are not precluded from serving as clinical instructors for therapy students, while providing services within their scope of work and performed under the direction and supervision of a licensed physical or occupational therapist to a Medicare beneficiary.

3. Services Provided Under Part A and Part B

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The payment methodologies for Part A and B therapy services rendered by a student are different. Under the MPFS (Medicare Part B), Medicare pays for services provided by physicians and practitioners that are specifically authorized by statute. Students do not meet the definition of practitioners under Medicare Part B. Under SNF PPS, payments are based upon the case mix or Resource Utilization Group (RUG) category that describes the patient. In the rehabilitation groups, the number of therapy minutes delivered to the patient determines the RUG category. Payment levels for each category are based upon the costs of caring for patients in each group rather than providing specific payment for each therapy service as is done in Medicare Part B.

230.1 - Practice of Physical Therapy

(Rev. 88, Issued: 05-07-08, Effective: 01-01-08, Implementation: 06-09-08)

A. General

Physical therapy services are those services provided within the scope of practice of physical therapists and necessary for the diagnosis and treatment of impairments, functional limitations, disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.) For descriptions of aquatic therapy in a community center pool see section 220C of this chapter.

B. Qualified Physical Therapist Defined

Reference: 42CFR484.4

The new personnel qualifications for physical therapists were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that a qualified physical therapist (PT) is a person who is licensed, if applicable, as a PT by the state in which he or she is practicing unless licensure does not apply, has graduated from an accredited PT education program and passed a national examination approved by the state in which PT services are provided. The phrase, "by the state in which practicing" includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The curriculum accreditation is provided by the Commission on Accreditation in Physical Therapy Education (CAPTE) or, for those who graduated before CAPTE, curriculum approval was provided by the American Physical Therapy Association (APTA). For internationally educated PTs, curricula are approved by a credentials evaluation organization either approved by the APTA or identified in 8 CFR 212.15(e) as it relates to PTs. For example, in 2007, 8 CFR 212.15(e) approved the credentials evaluation provided by the Federation of State Boards of Physical Therapy (FSBPT) and the Foreign Credentialing Commission on Physical Therapy (FCCPT). The requirements above apply to all PTs effective January 1, 2010, if they have not met any of the following requirements prior to January 1, 2010.

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Physical therapists whose current license was obtained on or prior to December 31, 2009, qualify to provide PT services to Medicare beneficiaries if they:

- graduated from a CAPTE approved program in PT on or before December 31, 2009 (examination is not required); or,

- graduated on or before December 31, 2009, from a PT program outside the U.S. that is determined to be substantially equivalent to a U.S. program by a credentials evaluating organization approved by either the APTA or identified in 8 CFR 212.15(e) and also passed an examination for PTs approved by the state in which practicing.

Or, PTs whose current license was obtained before January 1, 2008, may meet the requirements in place on that date (i.e., graduation from a curriculum approved by either the APTA, the Committee on Allied Health Education and Accreditation of the American Medical Association, or both).

Or, PTs meet the requirements who are currently licensed and were licensed or qualified as a PT on or before December 31, 1977, and had 2 years appropriate experience as a PT, and passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Or, PTs meet the requirements if they are currently licensed and before January 1, 1966, they were:

- admitted to membership by the APTA; or
- admitted to registration by the American Registry of Physical Therapists; or
- graduated from a 4-year PT curriculum approved by a State Department of Education; or
- licensed or registered and prior to January 1, 1970, they had 15 years of full-time experience in PT under the order and direction of attending and referring doctors of medicine or osteopathy.

Or, PTs meet requirements if they are currently licensed and they were trained outside the U.S. before January 1, 2008, and after 1928 graduated from a PT curriculum approved in the country in which the curriculum was located, if that country had an organization that was a member of the World Confederation for Physical Therapy, and that PT qualified as a member of the organization.

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For outpatient PT services that are provided incident to the services of physicians/NPPs, the requirement for PT licensure does not apply, all other personnel qualifications do apply. The qualified personnel providing PT services incident to the services of a physician/NPP must be trained in an accredited PT curriculum. For example, a person who, on or before December 31, 2009, graduated from a PT curriculum accredited by CAPTE, but who has not passed the national examination or obtained a license, could provide Medicare outpatient PT therapy services incident to the services of a physician/NPP if the physician assumes responsibility for the services according to the incident to policies. On or after January 1, 2010, although licensure does not apply, both education and examination requirements that are effective January 1, 2010, apply to qualified personnel who provide PT services incident to the services of a physician/NPP.

C. Services of Physical Therapy Support Personnel

Reference: 42CFR 484.4

Personnel Qualifications. The new personnel qualifications for physical therapist assistants (PTA) were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that a qualified PTA is a person who is licensed as a PTA unless licensure does not apply, is registered or certified, if applicable, as a PTA by the state in which practicing, and graduated from an approved curriculum for PTAs, and passed a national examination for PTAs. The phrase, “by the state in which practicing” includes

any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location or the entity billing for the services. Approval for the curriculum is provided by CAPTE or, if internationally or military trained PTAs apply, approval will be through a credentialing body for the curriculum for PTAs identified by either the American Physical Therapy Association or identified in 8 CFR 212.15(e). A national examination for PTAs is, for example the one furnished by the Federation of State Boards of Physical Therapy. These requirements above apply to all PTAs effective January 1, 2010, if they have not met any of the following requirements prior to January 1, 2010.

Those PTAs also qualify who, on or before December 31, 2009, are licensed, registered or certified as a PTA and met one of the two following requirements:

1. Is licensed or otherwise regulated in the state in which practicing; or

2. In states that have no licensure or other regulations, or where licensure does not apply, PTAs have:

- graduated on or before December 31, 2009, from a 2-year college-level program approved by the APTA or CAPTE; and

- effective January 1, 2010, those PTAs must have both graduated from a CAPTE approved curriculum and passed a national examination for PTAs; or

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PTAs may also qualify if they are licensed, registered or certified as a PTA, if applicable and meet requirements in effect before January 1, 2008, that is,

- they have graduated before January 1, 2008, from a 2 year college level program approved by the APTA; or

- on or before December 31, 1977, they were licensed or qualified as a PTA and passed a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Services. The services of PTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising physical therapist. PTAs may not provide evaluation services, make clinical judgments or decisions or take responsibility for the service. They act at the direction and under the supervision of the treating physical therapist and in accordance with state laws.

A physical therapist must supervise PTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for PTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation

agencies, and public health agencies, 42CFR485.713 indicates that when a PTA provides services, either on or off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of a PTA shall not be billed as services incident to a physician/NPP's service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., theraband, hand putty, electrodes) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the physical therapist, and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130.

Services provided by aides, even if under the supervision of a therapist, are not therapy services and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D. Application of Medicare Guidelines to PT Services

This subsection will be used in the future to illustrate the application of the above guidelines to some of the physical therapy modalities and procedures utilized in the treatment of patients.

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230.2 - Practice of Occupational Therapy

(Rev. 88, Issued: 05-07-08, Effective: 01-01-08, Implementation: 06-09-08)

A. General

Occupational therapy services are those services provided within the scope of practice of occupational therapists and necessary for the diagnosis and treatment of impairments, functional disabilities or changes in physical function and health status. (See Pub. 100-03, the Medicare National Coverage Determinations Manual, for specific conditions or services.)

Occupational therapy is medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning. Such therapy may involve:

The evaluation, and reevaluation as required, of a patient's level of function by administering diagnostic and prognostic tests;

The selection and teaching of task-oriented therapeutic activities designed to restore physical function; e.g., use of woodworking activities on an inclined table to restore shoulder, elbow, and wrist range of motion lost as a result of burns;

The planning, implementing, and supervising of individualized therapeutic activity programs as part of an overall "active treatment" program for a patient with a diagnosed psychiatric illness; e.g., the use of sewing activities which require following a pattern to reduce confusion and restore reality orientation in a schizophrenic patient;

The planning and implementing of therapeutic tasks and activities to restore sensory-integrative function; e.g., providing motor and tactile activities to increase sensory input and improve response for a stroke patient with functional loss resulting in a distorted body image;

The teaching of compensatory technique to improve the level of independence in the activities of daily living, for example:

- Teaching a patient who has lost the use of an arm how to pare potatoes and chop vegetables with one hand;
- Teaching an upper extremity amputee how to functionally utilize a prosthesis;
- Teaching a stroke patient new techniques to enable the patient to perform feeding, dressing, and other activities as independently as possible; or
- Teaching a patient with a hip fracture/hip replacement techniques of standing tolerance and balance to enable the patient to perform such functional activities as dressing and homemaking tasks.

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The designing, fabricating, and fitting of orthotics and self-help devices; e.g., making a hand splint for a patient with rheumatoid arthritis to maintain the hand in a functional position or constructing a device which would enable an individual to hold a utensil and feed independently; or

Vocational and prevocational assessment and training, subject to the limitations specified in item B below.

Only a qualified occupational therapist has the knowledge, training, and experience required to evaluate and, as necessary, reevaluate a patient's level of function, determine whether an occupational therapy program could reasonably be expected to improve, restore, or compensate for lost function and, where appropriate, recommend to the physician/NPP a plan of treatment.

B. Qualified Occupational Therapist Defined

Reference: 42CFR484.4

The new personnel qualifications for occupational therapists (OT) were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that a qualified OT is an individual who is licensed, if licensure applies, or otherwise regulated, if applicable, as an OT by the state in which practicing, and graduated from an accredited education program for OTs, and is eligible to take or has passed the examination for OTs administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT). The phrase, "by the state in which practicing" includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services. The education program for U.S. trained OTs is accredited by the Accreditation Council for Occupational Therapy Education (ACOTE). The requirements above apply to all OTs effective January 1, 2010, if they have not met any of the following requirements prior to January 1, 2010.

The OTs may also qualify if on or before December 31, 2009:

- they are licensed or otherwise regulated as an OT in the state in which practicing (regardless of the qualifications they met to obtain that licensure or regulation); or

- when licensure or other regulation does not apply, OTs have graduated from an OT education program accredited by ACOTE and are eligible to take, or have successfully completed the NBCOT examination for OTs.

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Also, those OTs who met the Medicare requirements for OTs that were in 42CFR484.4 prior to January 1, 2008, qualify to provide OT services for Medicare beneficiaries if:

- on or before January 1, 2008, they graduated an OT program approved jointly by the American Medical Association and the AOTA, or

- they are eligible for the National Registration Examination of AOTA or the National Board for Certification in OT.

Also, they qualify who on or before December 31, 1977, had 2 years of appropriate experience as an occupational therapist, and had achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

Those educated outside the U.S. may meet the same qualifications for domestic trained OTs. For example, they qualify if they were licensed or otherwise regulated by the state in which practicing on or before December 31, 2009. Or they are qualified if they:

- graduated from an OT education program accredited as substantially equivalent to a U.S. OT education program by ACOTE, the World Federation of Occupational Therapists, or a credentialing body approved by AOTA; and

- passed the NBCOT examination for OT; and

- Effective January 1, 2010, are licensed or otherwise regulated, if applicable as an OT by the state in which practicing.

For outpatient OT services that are provided incident to the services of physicians/NPPs, the requirement for OT licensure does not apply; all other personnel qualifications do apply. The qualified personnel providing OT services incident to the services of a physician/NPP must be trained in an accredited OT curriculum. For example, a person who, on or before December 31, 2009, graduated from an OT curriculum accredited by ACOTE and is eligible to take or has successfully completed the entry-level certification examination for OTs developed and administered by NBCOT, could provide Medicare outpatient OT services incident to the services of a physician/NPP if the physician assumes responsibility for the services according to the incident to policies. On or after January 1, 2010, although licensure does not apply, both education and examination requirements that are effective January 1, 2010, apply to qualified personnel who provide OT services incident to the services of a physician/NPP.

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C. Services of Occupational Therapy Support Personnel

Reference: 42CFR 484.4

The new personnel qualifications for occupational therapy assistants were discussed in the 2008 Physician Fee Schedule. See the Federal Register of November 27, 2007, for the full text. See also the correction notice for this rule, published in the Federal Register on January 15, 2008.

The regulation provides that an occupational therapy assistant is a person who is licensed, unless licensure does not apply, or otherwise regulated, if applicable, as an OTA by the state in which practicing, and graduated from an OTA education program accredited by ACOTE and is eligible to take or has successfully completed the NBCOT examination for OTAs. The phrase, “by the state in which practicing” includes any authorization to practice provided by the same state in which the service is provided, including temporary licensure, regardless of the location of the entity billing the services.

If the requirements above are not met, an OTA may qualify if, on or before December 31, 2009, the OTA is licensed or otherwise regulated as an OTA, if applicable, by the state in which practicing, or meets any qualifications defined by the state in which practicing.

Or, where licensure or other state regulation does not apply, OTAs may qualify if they have, on or before December 31, 2009:

- completed certification requirements to practice as an OTA established by a credentialing organization approved by AOTA; and

- after January 1, 2010, they have also completed an education program accredited by ACOTE and passed the NBCOT examination for OTAs.

OTAs who qualified under the policies in effect prior to January 1, 2008, continue to qualify to provide OT directed and supervised OTA services to Medicare beneficiaries. Therefore, OTAs qualify who after December 31, 1977, and on or before December 31, 2007:

- completed certification requirements to practice as an OTA established by a credentialing organization approved by AOTA; or

- completed the requirements to practice as an OTA applicable in the state in which practicing.

Those OTAs who were educated outside the U.S. may meet the same requirements as domestically trained OTAs. Or, if educated outside the U.S. on or after January 1, 2008, they must have graduated from an OTA program accredited as substantially equivalent to OTA entry level education in the U.S. by ACOTE, its successor organization, or the World Federation of Occupational Therapists or a credentialing body approved by AOTA. In addition, they must have passed an exam for OTAs administered by NBCOT.

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<u>Services.</u> The services of OTAs used when providing covered therapy benefits are included as part of the covered service. These services are billed by the supervising occupational therapist. OTAs may not provide evaluation services, make clinical judgments or decisions or take responsibility for the service. They act at the direction and under the supervision of the treating occupational therapist and in accordance with state laws.

An occupational therapist must supervise OTAs. The level and frequency of supervision differs by setting (and by state or local law). General supervision is required for OTAs in all settings except private practice (which requires direct supervision) unless state practice requirements are more stringent, in which case state or local requirements must be followed. See specific settings for details. For example, in clinics, rehabilitation agencies, and public health agencies, 42CFR485.713 indicates that when an OTA provides services, either on or off the organization's premises, those services are supervised by a qualified occupational therapist who makes an onsite supervisory visit at least once every 30 days or more frequently if required by state or local laws or regulation.

The services of an OTA shall not be billed as services incident to a physician/NPP's service, because they do not meet the qualifications of a therapist.

The cost of supplies (e.g., looms, ceramic tiles, or leather) used in furnishing covered therapy care is included in the payment for the HCPCS codes billed by the occupational therapist and are, therefore, not separately billable. Separate coverage and billing provisions apply to items that meet the definition of brace in §130 of this manual.

Services provided by aides, even if under the supervision of a therapist, are not therapy services in the outpatient setting and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services that are unskilled are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D. Application of Medicare Guidelines to Occupational Therapy Services

Occupational therapy may be required for a patient with a specific diagnosed psychiatric illness. If such services are required, they are covered assuming the coverage criteria are met. However, where an individual's motivational needs are not related to a specific diagnosed psychiatric illness, the meeting of such needs does not usually require an individualized therapeutic program. Such needs can be met through general activity programs or the efforts of other professional personnel involved in the care of the patient. Patient motivation is an appropriate and inherent function of all health disciplines, which is interwoven with other functions performed by such personnel for the patient. Accordingly, since the special skills of an occupational therapist are not required, an occupational therapy program for individuals who do not have a specific diagnosed psychiatric illness is not to be considered reasonable and necessary for the treatment of an illness or injury. Services furnished under such a program are not covered.

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Occupational therapy may include vocational and prevocational assessment and training. When services provided by an occupational therapist are related solely to specific employment opportunities, work skills, or work settings, they are not reasonable or necessary for the diagnosis or treatment of an illness or injury and are not covered. However, carriers and intermediaries exercise care in applying this exclusion, because the assessment of level of function and the teaching of compensatory techniques to improve the level of function, especially in activities of daily living, are services which occupational therapists provide for both vocational and nonvocational purposes. For example, an assessment of sitting and standing tolerance might be nonvocational for a mother of young children or a retired individual living alone, but could also be a vocational test for a sales clerk. Training an amputee in the use of prosthesis for telephoning is necessary for everyday activities as well as for employment purposes. Major changes in life style may be mandatory for an individual with a substantial disability. The techniques of adjustment cannot be considered exclusively vocational or nonvocational.

230.3 - Practice of Speech-Language Pathology

(Rev. 106, Issued: 04-24-09, Effective: 07-01-09, Implementation: 07-06-09)

A. General

Speech-language pathology services are those services provided within the scope of practice of speech-language pathologists and necessary for the diagnosis and treatment of speech and language disorders, which result in communication disabilities and for the diagnosis and treatment of swallowing disorders (dysphagia), regardless of the presence of a communication disability. (See Pub. 100-03, chapter 1, §170.3) See section 230.4 of this chapter for benefit policies on speech-language pathologists in private practice (SLPP). See Pub. 100-08, Medicare Program Integrity Manual, chapter 10, section 12.4.14 for policy on enrollment in an SLPP.

B. Qualified Speech-Language Pathologist Defined

A qualified speech-language pathologist for program coverage purposes meets one of the following requirements:

- The education and experience requirements for a Certificate of Clinical Competence in (speech-language pathology) granted by the American Speech-Language Hearing Association; or

- Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

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For outpatient speech-language pathology services that are provided incident to the services of physicians/NPPs, the requirement for speech-language pathology licensure does not apply; all other personnel qualifications do apply. Therefore, qualified personnel providing speech-language pathology services incident to the services of a physician/NPP must meet the above qualifications.

C. Services of Speech-Language Pathology Support Personnel

Services of speech-language pathology assistants are not recognized for Medicare coverage. Services provided by speech-language pathology assistants, even if they are licensed to provide services in their states, will be considered unskilled services and denied as not reasonable and necessary if they are billed as therapy services.

Services provided by aides, even if under the supervision of a therapist, are not therapy services and are not covered by Medicare. Although an aide may help the therapist by providing unskilled services, those services are not covered by Medicare and shall be denied as not reasonable and necessary if they are billed as therapy services.

D. Application of Medicare Guidelines to Speech-Language Pathology Services

1. Evaluation Services

Speech-language pathology evaluation services are covered if they are reasonable and necessary and not excluded as routine screening by §1862(a)(7) of the Act. The speech-

language pathologist employs a variety of formal and informal speech, language, and dysphagia assessment tests to ascertain the type, causal factor(s), and severity of the speech and language or swallowing disorders. Reevaluation of patients for whom speech, language and swallowing were previously contraindicated is covered only if the patient exhibits a change in medical condition. However, monthly reevaluations; e.g., a Western Aphasia Battery, for a patient undergoing a rehabilitative speech-language pathology program, are considered a part of the treatment session and shall not be covered as a separate evaluation for billing purposes. Although hearing screening by the speech-language pathologist may be part of an evaluation, it is not billable as a separate service.

2. Therapeutic Services

The following are examples of common medical disorders and resulting communication deficits, which may necessitate active rehabilitative therapy. This list is not all-inclusive:

> Cerebrovascular disease such as cerebral vascular accidents presenting with dysphagia, aphasia/dysphasia, apraxia, and dysarthria;
>
> Neurological disease such as Parkinsonism or Multiple Sclerosis with dysarthria, dysphagia, inadequate respiratory volume/control, or voice disorder; or
>
> Laryngeal carcinoma requiring laryngectomy resulting in aphonia.

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3. Impairments of the Auditory System

The terms, aural rehabilitation, auditory rehabilitation, auditory processing, lipreading and speech reading are among the terms used to describe covered services related to perception and comprehension of sound through the auditory system. See Pub. 100-04, chapter 12, section 30.3 for billing instructions. For example:

- Auditory processing evaluation and treatment may be covered and medically necessary. Examples include but are not limited to services for certain neurological impairments or the absence of natural auditory stimulation that results in impaired ability to process sound. Certain auditory processing disorders require diagnostic audiological tests in addition to speech-language pathology evaluation and treatment.

- Evaluation and treatment for disorders of the auditory system may be covered and medically necessary, for example, when it has been determined by a speech-language pathologist in collaboration with an audiologist that the hearing impaired beneficiary's current amplification options (hearing aid, other amplification device or cochlear implant) will not sufficiently meet the patient's functional communication needs. Audiologists and speech-language pathologists both evaluate beneficiaries for disorders of the auditory system using different skills and techniques, but only speech-language pathologists may provide treatment.

Assessment for the need for rehabilitation of the auditory system (but not the vestibular system) may be done by a speech language pathologist. Examples include but are not limited to: evaluation of comprehension and production of language in oral, signed or written modalities, speech and voice production, listening skills, speech reading, communications strategies, and the impact of the hearing loss on the patient/client and family.

Examples of rehabilitation include but are not limited to treatment that focuses on comprehension, and production of language in oral, signed or written modalities; speech and voice production, auditory training, speech reading, multimodal (e.g., visual, auditory-visual, and tactile) training, communication strategies, education and counseling. In determining the necessity for treatment, the beneficiary's performance in both clinical and natural environment should be considered.

4. Dysphagia

Dysphagia, or difficulty in swallowing, can cause food to enter the airway, resulting in coughing, choking, pulmonary problems, aspiration or inadequate nutrition and hydration with resultant weight loss, failure to thrive, pneumonia and death. It is most often due to complex neurological and/or structural impairments including head and neck trauma, cerebrovascular accident, neuromuscular degenerative diseases, head and neck cancer, dementias, and encephalopathies. For these reasons, it is important that only qualified professionals with specific training and experience in this disorder provide evaluation and treatment.

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The speech-language pathologist performs clinical and instrumental assessments and analyzes and integrates the diagnostic information to determine candidacy for intervention as well as appropriate compensations and rehabilitative therapy techniques. The equipment that is used in the examination may be fixed, mobile or portable. Professional guidelines recommend that the service be provided in a team setting with a physician/NPP who provides supervision of the radiological examination and interpretation of medical conditions revealed in it.

Swallowing assessment and rehabilitation are highly specialized services. The professional rendering care must have education, experience and demonstrated competencies. Competencies include but are not limited to: identifying abnormal upper aerodigestive tract structure and function; conducting an oral, pharyngeal, laryngeal and respiratory function examination as it relates to the functional assessment of swallowing; recommending methods of oral intake and risk precautions; and developing a treatment plan employing appropriate compensations and therapy techniques.

230.4 - Services Furnished by a Therapist in Private Practice (TPP)

(Rev. 106, Issued: 04-24-09, Effective: 07-01-09, Implementation: 07-06-09)

A. General

See section 220 of this chapter for definitions. Therapist refers only to a qualified physical therapist, occupational therapist or speech-language pathologist. TPP refers to therapists in private practice (qualified physical therapists, occupational therapists and speech-language pathologists).

In order to qualify to bill Medicare directly as a therapist, each individual must be enrolled as a private practitioner and employed in one of the following practice types: an unincorporated solo practice, unincorporated partnership, unincorporated group practice, physician/NPP group or groups that are not professional corporations, if allowed by state and local law. Physician/NPP group practices may employ TPP if state and local law permits this employee relationship.

For purposes of this provision, a physician/NPP group practice is defined as one or more physicians/NPPs enrolled with Medicare who may bill as one entity. For further details on issues concerning enrollment, see the provider enrollment Web site at www.cms.hhs.gov/MedicareProviderSupEnroll and Pub. 100-08, Medicare Program Integrity Manual, chapter10, section 12.4.14.

Private practice also includes therapists who are practicing therapy as employees of another supplier, of a professional corporation or other incorporated therapy practice. Private practice does not include individuals when they are working as employees of an institutional provider.

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Services should be furnished in the therapist's or group's office or in the patient's home. The office is defined as the location(s) where the practice is operated, in the state(s) where the therapist (and practice, if applicable) is legally authorized to furnish services, during the hours that the therapist engages in the practice at that location. If services are furnished in a private practice office space, that space shall be owned, leased, or rented by the practice and used for the exclusive purpose of operating the practice. For descriptions of aquatic therapy in a community center pool see section 220C of this chapter.

Therapists in private practice must be approved as meeting certain requirements, but do not execute a formal provider agreement with the Secretary.

If therapists who have their own Medicare National Provider Identifier (NPI) are employed by therapist groups, physician/NPP groups, or groups that are not professional organizations, the requirement that therapy space be owned, leased, or rented may be satisfied by the group that employs the therapist. Each therapist employed by a group should enroll as a TPP.

When therapists with a Medicare NPI provide services in the physician's/NPP's office in which they are employed, and bill using their NPI for each therapy service, then the direct supervision requirement for enrolled staff apply.

When the therapist who has a Medicare NPI is employed in a physician's/NPP's office the services are ordinarily billed as services of the therapist, with the therapist identified on the claim as the supplier of services. However, services of the therapist who has a Medicare NPI may also be billed by the physician/NPP as services incident to the physician's/NPP's service. (See §230.5 for rules related to therapy services incident to a physician.) In that case, the physician/NPP is the supplier of service, the NPI of the supervising physician/NPP is reported on the claim with the service and all the rules for both therapy services and incident to services (§230.5) must be followed.

B. Private Practice Defined

Reference: **Federal Register** November, 1998, pages 58863-58869; 42CFR 410.38(b), 42CFR410.59, 42CFR410.60, 42CFR410.62

The contractor considers a therapist to be in private practice if the therapist maintains office space at his or her own expense and furnishes services only in that space or the patient's home. Or, a therapist is employed by another supplier and furnishes services in facilities provided at the expense of that supplier.

The therapist need not be in full-time private practice but must be engaged in private practice on a regular basis; i.e., the therapist is recognized as a private practitioner and for that purpose has access to the necessary equipment to provide an adequate program of therapy.

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The therapy services must be provided either by or under the direct supervision of the TPP. Each TPP should be enrolled as a Medicare provider. If a therapist is not enrolled, the services of that therapist must be directly supervised by an enrolled therapist. Direct supervision requires that the supervising private practice therapist be present in the office suite at the time the service is performed. These direct supervision requirements apply only in the private practice setting and only for therapists and their assistants. In other outpatient settings, supervision rules differ. The services of support personnel must be included in the therapist's bill. The supporting personnel, including other therapists, must be W-2 or 1099 employees of the TPP or other qualified employer.

Coverage of outpatient therapy under Part B includes the services of a qualified TPP when furnished in the therapist's office or the beneficiary's home. For this purpose, "home" includes an institution that is used as a home, but not a hospital, CAH or SNF, (**Federal Register** Nov. 2, 1998, pg 58869). Place of Service (POS) includes:

- 03/School, only if residential,
- 04/Homeless Shelter,
- 12/Home, other than a facility that is a private residence,
- 14/Group Home,
- 33/Custodial Care Facility.

C. Assignment

Reference: Nov. 2, 1998 **Federal Register**, pg. 58863
See also Pub. 100-04 chapter 1, §30.2.

When physicians, NPPs, or TPPs obtain provider numbers, they have the option of accepting assignment (participating) or not accepting assignment (nonparticipating). In contrast, providers, such as outpatient hospitals, SNFs, rehabilitation agencies, and CORFs, do not have the option. For these providers, assignment is mandatory.

If physicians/NPPs, or TPPs accept assignment (are participating), they must accept the Medicare Physician Fee Schedule amount as payment. Medicare pays 80% and the patient is responsible for 20%. In contrast, if they do not accept assignment, Medicare will only pay 95% of the fee schedule amount. However, when these services are not furnished on an assignment-related basis, the limiting charge applies. (See §1848(g)(2)(c) of the Act.)

NOTE: Services furnished by a therapist in the therapist's office under arrangements with hospitals in rural communities and public health agencies (or services provided in the beneficiary's home under arrangements with a provider of outpatient physical or occupational therapy services) are not covered under this provision. See section 230.6.

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230.5 - Physical Therapy, Occupational Therapy and Speech-Language Pathology Services Provided Incident to the Services of Physicians and Non-Physician Practitioners (NPP)

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

References: §1861(s)(2)(A) of the Act
42 CFR 410.10(b)
42 CFR 410.26
Pub. 100-02, ch. 15, §60.

<u>The Benefit.</u> Therapy services have their own benefit under §1861 of the Social Security Act and shall be covered when provided according to the standards and conditions of the benefit described in Medicare manuals. The statute 1862(a)(20) requires that payment be made for a therapy service billed by a physician/NPP only if the service meets the standards and conditions--other than licensing--that would apply to a therapist. (For example, see coverage requirements in Pub. 100-08, chapter 13, §13.5.1(C), Pub. 100-04, chapter 5, and also the requirements of this manual, §<u>220</u> and §<u>230</u>.

<u>Incident to a Therapist.</u> There is no coverage for services provided incident to the services of a therapist. Although PTAs and OTAs work under the supervision of a therapist and their services may be billed by the therapist, their services are covered under the benefit for therapy services and not by the benefit for services incident to a physician/NPP. The services furnished by PTAs and OTAs are not incident to the therapist's service.

Qualifications of Auxiliary Personnel. Therapy services appropriately billed incident to a physician's/NPP's service shall be subject to the same requirements as therapy services that would be furnished by a physical therapist, occupational therapist or speech-language pathologist in any other outpatient setting with one exception. When therapy services are performed incident to a physician's/NPP's service, the qualified personnel who perform the service do not need to have a license to practice therapy, unless it is required by state law. The qualified personnel must meet all the other requirements except licensure. Qualifications for therapists are found in 42CFR484.4 and in section 230.1, 230.2, and 230.3 of this manual. In effect, these rules require that the person who furnishes the service to the patient must, at least, be a graduate of a program of training for one of the therapy services as described above. Regardless of any state licensing that allows other health professionals to provide therapy services, Medicare is authorized to pay only for services provided by those trained specifically in physical therapy, occupational therapy or speech-language pathology. That means that the services of athletic trainers, massage therapists, recreation therapists, kinesiotherapists, low vision specialists or any other profession may not be billed as therapy services.

The services of PTAs and OTAs also may not be billed incident to a physician's/NPP's service. However, if a PT and PTA (or an OT and OTA) are both employed in a physician's office, the services of the PTA, when directly supervised by the PT or the services of the OTA, when directly supervised by the OT may be billed by the physician group as PT or OT services using the PIN/NPI of the enrolled PT (or OT). (See Section 230.4 for private practice rules on billing services performed in a physician's office.) If the PT or OT is not enrolled, Medicare shall not pay for the services of a PTA or OTA billed incident to the physician's service, because they do not meet the qualification standards in 42CFR484.4.

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Therapy services provided and billed incident to the services of a physician/NPP also must meet all incident-to requirements in this manual in chapter 15, §60. Where the policies have different requirements, the more stringent requirement shall be met.

For example, when therapy services are billed as incident to a physician/NPP services, the requirement for direct supervision by the physician/NPP and other incident to requirements must be met, even though the service is provided by a licensed therapist who may perform the services unsupervised in other settings.

The mandatory assignment provision does not apply to therapy services furnished by a physician/NPP or "incident to" a physician's/NPP's service. However, when these services are not furnished on an assignment-related basis; the limiting charge applies.

For emphasis, following are some of the standards that apply to therapy services billed incident-to the services of a physician/NPP in the physician's/NPP's office or the beneficiary's residence.

A. Therapy services provided to the beneficiary must be covered and payable outpatient rehabilitation services as described, for example, in this section as well as Pub. 100-08, chapter 13, §13.5.1.

B. Therapy services must be provided by, or under the direct supervision of a physician (a doctor of medicine or osteopathy) or NPP who is legally authorized to practice therapy services by the state in which he or she performs such function or action. Direct supervision requirements are the same as in 42CFR410.32(b)(3). The supervisor must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician/NPP must be present in the same room in the office where the service is performed.

C. The services must be of a level of complexity that require that they be performed by a therapist or under the direct supervision of the therapist, physician/NPP who is licensed to perform them. Services that do not require the performance or supervision of the therapist, physician/NPP, are not considered reasonable or necessary therapy services even if they are performed or supervised by a physician/NPP or other qualified professional.

D. Services must be furnished under a plan of treatment as in §220.1.2 of this chapter. The services provided must relate directly to the physician/NPP service to which it is incident.

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230.6 - Therapy Services Furnished Under Arrangements With Providers and Clinics

(Rev. 36, Issued: 06-24-05, Effective: 06-06-05, Implementation: 06-06-05)

References: See also Pub. 100-01, chapter 5, §10.3.

A. General

For rules regarding services provided under arrangement, see Pub. 100-01, chapter 5, §10.3.

A provider may have others furnish outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services through arrangements under which receipt of payment by the provider for the services discharges the liability of the beneficiary or any other person to pay for the service.

However, it is not intended that the provider merely serve as a billing mechanism for the other party. For such services to be covered the provider must assume professional responsibility for the services.

The provider's professional supervision over the services requires application of many of the same controls that are applied to services furnished by salaried employees. The provider must:

- Accept the patient for treatment in accordance with its admission policies;
- Maintain a complete and timely clinical record on the patient which includes diagnosis, medical history, orders, and progress notes relating to all services received;
- Maintain liaison with the attending physician/NPP with regard to the progress of the patient and to assure that the required plan of treatment is periodically reviewed by the physician/NPP;
- Secure from the physician/NPP the required certifications and recertifications; and
- Ensure that the medical necessity of such service is reviewed on a sample basis by the agency's staff or an outside review group.

In addition, when a provider provides outpatient services under an arrangement with others, such services must be furnished in accordance with the terms of a written contract, which provides for retention by the provider of responsibility for and control and supervision of such services. The terms of the contract should include at least the following:

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- Provide that the therapy services are to be furnished in accordance with the plan of care established according to Medicare policies for therapy plans of care in section 220.1.2 of this chapter;
- Specify the geographical areas in which the services are to be furnished;
- Provide that contracted personnel and services meet the same requirements as those which would be applicable if the personnel and services were furnished directly by the provider;
- Provide that the therapist will participate in conferences required to coordinate the care of an individual patient;
- Provide for the preparation of treatment records, with progress notes and observations, and for the prompt incorporation of such into the clinical records of the clinic;
- Specify the financial arrangements. The contracting organization or individual may not bill the patient or the health insurance program; and

- Specify the period of time the contract is to be in effect and the manner of termination or renewal.

B. Special Rules for Hospitals

- A hospital may bill Medicare for outpatient therapy (physical therapy, occupational therapy, or speech-language pathology) services that it furnishes to its outpatients either directly or under arrangements in the hospital's outpatient department. If a hospital furnishes medically necessary therapy services in its outpatient department to individuals who are registered as its outpatients, those services must be billed directly by the hospital using bill type 13X or 85X for critical access hospitals. Note that services provided to residents of a Medicare-certified SNF may not be billed by the hospital as services to its outpatients.

- When a hospital sends its therapists to the home of an individual who is registered as an outpatient of the hospital but who is unable, for medical reasons, to come to the hospital to receive medically necessary therapy services, the services must meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals. The hospital may bill for those services directly using bill type 13X or 85X for critical access hospitals.

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- If a hospital sends its therapists to provide therapy services to individuals who are registered as its outpatients and who are residing in the non-certified part of a SNF, or in another residential setting (e.g., a group home, assisted living facility or domiciliary care home), the hospital may bill for the services as hospital outpatient services if the services meet the requirements applicable to outpatient hospital therapy services, as set forth in the regulations and applicable Medicare manuals.

- A hospital may make an arrangement with another entity such as an Outpatient Rehab Facility (Rehabilitation Agency) or a private practice, to provide therapy services to individuals who are registered as outpatients of the hospital. These services must meet the requirements applicable to services furnished under arrangements and the requirements applicable to the outpatient hospital therapy services as set forth in the regulations and applicable Medicare manuals. The hospital uses bill type 13X or 85X for critical access hospitals to bill for the services that another entity furnishes under arrangement to its outpatients.

- Where the provider is a public health agency or a hospital in a rural community, it may enter into arrangements to have outpatient physical therapy services furnished in the private office of a qualified physical therapist if the agency or hospital does not have the capacity to provide on its premises all of the modalities of treatment, tests, and measurements that are included in

an adequate outpatient physical therapy program and the services and modalities which the public health agency or hospital cannot provide on its premises are not available on an outpatient basis in another accessible certified facility.

- In certain settings and under certain circumstances, hospitals may not bill Medicare for therapy services as services of the hospital:

  - If a hospital sends its therapists to provide therapy services to patients of another hospital, including a patient at an inpatient rehabilitation facility or a long term care facility, the services must be furnished under arrangements made with the hospital sending the therapists by the hospital having the patients and billed as hospital services by the facility whose patients are treated. These services would be subject to existing hospital bundling rules and would be paid under the payment method applicable to the hospital at which the individuals are patients.

  - A hospital may not send its therapists to provide therapy services to individuals who are receiving services from an HHA under a home health plan of care and bill for the therapy services as hospital outpatient services. For patients under a home health plan of care, payment for therapy services (unless provided by physicians/NPPs) is included or bundled into Medicare's episodic payment to the HHA, and those services must be billed by the HHA under the HHA consolidated billing rules. For patients receiving HHA services under an HHA plan of care, therapy services must be furnished directly or under arrangements made by the HHA, and only the HHA may bill for those services.

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  - If a hospital sends its therapists to provide services under arrangements made by a SNF to residents of the Medicare-certified part of a SNF, SNF consolidated billing rules apply. For arrangements specific to SNF Part A, see Pub. 100-04, chapter 6, §10.4. This means that therapy services furnished to SNF residents in the Medicare-certified part of a SNF cannot be billed by any entity other than the SNF. Therefore, a hospital may not bill Medicare for PT/OT/SLP services furnished to residents of a Medicare-certified part of a SNF by its therapists as services of the hospital.

NOTE: If the SNF resident is in a covered Part A stay, the therapy services would be included in the SNF's global PPS per diem payment for the covered Part A stay itself. If the resident is in a noncovered stay (Part A benefits exhausted, no prior qualifying hospital stay, etc.), but remains in the Medicare-certified part of a SNF, the SNF would submit the Part B therapy bill to its fiscal intermediary.

SNF Setting	Applicable Rules

Medicare Part A or B	Consolidated Billing Rules Apply?	Hospital May Bill For Outpatient Services?
Part A (Medicare Covered / PPS) Resident in Medicare-certified part of a SNF	Yes	No
Medicare Part B Resident in Medicare-certified part of a SNF	Yes	No
Medicare Part B Not a Resident in Medicare-certified part of a SNF	No	Yes

- A hospital may not send therapy staff to provide therapy services in non-residential health care settings and bill for the services as if they were provided at the hospital, even if the hospital owns the other facility or entity. Examples of such non-residential settings include CORFs, rehabilitation agencies, ORFs and offices of physicians/NPPs or other practitioners, such as physical therapists. For example, services furnished to patients of a CORF must be billed as CORF services and not as outpatient hospital services. Even if a CORF contracts with a hospital to furnish services to CORF patients, the hospital may not bill Medicare for the services as hospital outpatient services. However, the CORF could have the hospital furnish services to its patients under arrangements, in which case the CORF would bill for the services.

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Psychiatric hospitals are treated the same as other hospitals for the purpose of therapy billing.

231 - Pulmonary Rehabilitation (PR) Program Services Furnished On or After January 1, 2010

(Rev. 124, Issued: 05-07-10, Effective: 01-01-10, Implementation: 10-04-10)

A pulmonary rehabilitation (PR) program is typically a physician-supervised, multidisciplinary program individually tailored and designed to optimize physical and social performance and autonomy of care for patients with chronic respiratory impairment. The main goal is to empower the individuals' ability to exercise independently. Exercise is combined with other training and support mechanisms to encourage long-term adherence to the treatment plan. Effective January 1, 2010, Medicare Part B pays for PR programs and related items and services if specific criteria is met by the Medicare beneficiary, the PR program itself, the setting in which it is administered, and the physician administering the program, as outlined below:

PR Program Beneficiary Requirements:

As specified in 42 CFR 410.47, Medicare covers PR items and services for patients with moderate to very severe chronic obstructive pulmonary disease (COPD) (defined as GOLD classification II, III, and IV), when referred by the physician treating the chronic respiratory disease. Additional medical indications for coverage for PR program services may be established through the national coverage determination process.

PR Program Component Requirements:

- Physician-prescribed exercise. This physical activity includes techniques such as exercise conditioning, breathing retraining, and step and strengthening exercises. Some aerobic exercise must be included in each PR session. Both low- and high-intensity exercise is recommended to produce clinical benefits and a combination of endurance and strength training should be conducted at least twice per week.

- Education or training. This should be closely and clearly related to the individual's care and treatment and tailored to the individual's needs, including information on respiratory problem management and, if appropriate, brief smoking cessation counseling. Any education or training must assist in achievement of individual goals towards independence in activities of daily living, adaptation to limitations, and improved quality of life (QoL).

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- Psychosocial assessment. This assessment means a written evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition. It should include: (1) an assessment of those aspects of the individual's family and home situation that affects the individual's rehabilitation treatment, and, (2) a psychological evaluation of the individual's response to, and rate of progress under, the treatment plan. Periodic re-evaluations are necessary to ensure the individual's psychosocial needs are being met.

- Outcomes assessment. These should include: (1) beginning and end evaluations based on patient-centered outcomes, which are conducted by the physician at the start and end of the program, and, (2) objective clinical measures of the effectiveness of the PR program for the individual patient, including exercise performance and self-reported measures of shortness of breath, and behavior. The assessments should include clinical measures such as the 6-minute walk, weight, exercise performance, self-reported dyspnea, behavioral measures (supplemental oxygen use, smoking status,) and a QoL assessment.

- An individualized treatment plan describing the individual's diagnosis and detailing how components are utilized for each patient. The plan must be established, reviewed, and signed by a physician every 30 days. The plan may initially be developed by the referring physician or the PR physician. If the plan

is developed by the referring physician who is not the PR physician, the PR physician must also review and sign the plan prior to imitation of the PR program. It is expected that the supervising physician would have initial, direct contact with the individual prior to subsequent treatment by ancillary personnel, and also have at least one direct contact in each 30-day period. The plan must have written specificity with regards to the type, amount, frequency, and duration of PR items and services furnished to the individual, and specify the appropriate mix of services for the patient's needs. It must include measurable and expected outcomes and estimated timetables to achieve these outcomes.

As specified at 42 CFR 410.47(f), PR program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if medically necessary.

PR Program Setting Requirements:

PR items and services must be furnished in a physician's office or a hospital outpatient setting. The setting must have the necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and a defibrillator) to treat chronic respiratory disease. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times that the PR items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision of physician office services as specified at 42 CFR 410.26, and for hospital outpatient therapeutic services as specified at 42 CFR 410.27.

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PR Program Physician Requirements:

Medicare Part B pays for PR services supervised by a physician only if the physician meets all of the following requirements: (1) expertise in the management of individuals with respiratory pathophysiology, (2) licensed to practice medicine in the state in which the PR program is offered, (3) responsible and accountable for the PR program, and, (4) involved substantially, in consultation with staff, in directing the progress of the individual in the PR program.

(See Publication 100-04, Claims Processing Manual, chapter 32, section 140.4, for specific claims processing, coding, and billing requirements for PR program services.)

232 - Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

(Rev. 126, Issued: 05-21-10, Effective: 01-01-10, Implementation: 10-04-10)

Cardiac rehabilitation (CR) services mean a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment, outcomes assessment,

and other items/services as determined by the Secretary under certain conditions. Intensive cardiac rehabilitation (ICR) services mean a physician-supervised program that furnishes the same items/services under the same conditions as a CR program but must also demonstrate, as shown in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c). Effective January 1, 2010, Medicare Part B pays for CR/ICR programs and related items/services if specific criteria is met by the Medicare beneficiary, the CR/ICR program itself, the setting in which is it administered, and the physician administering the program, as outlined below:

CR/ICR Program Beneficiary Requirements:

Medicare covers CR/ICR program services for beneficiaries who have experienced one or more of the following:

- Acute myocardial infarction within the preceding 12 months;
- Coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- Heart or heart-lung transplant.
- For CR only, other cardiac conditions as specified through a national coverage determination (NCD).

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CR/ICR Program Component Requirements:

- Physician-prescribed exercise. This physical activity includes aerobic exercise combined with other types of exercise (i.e., strengthening, stretching) as determined to be appropriate for individual patients by a physician each day CR/ICR items/services are furnished.

- Cardiac risk factor modification. This includes education, counseling, and behavioral intervention, tailored to the patients' individual needs.

- Psychosocial assessment. This assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation. It should include: (1) an assessment of those aspects of the individual's family and home situation that affects the individual's rehabilitation treatment, and, (2) a psychosocial evaluation of the individual's response to, and rate of progress under, the treatment plan.

- Outcomes assessment. These should include: (i) minimally, assessments from the commencement and conclusion of CR/ICR, based on patient-centered outcomes which must be measured by the physician immediately at the beginning and end of the program, and, (ii) objective clinical measures of the effectiveness of the CR/ICR

program for the individual patient, including exercise performance and self-reported measures of exertion and behavior.

- Individualized treatment plan. This plan should be written and tailored to each individual patient and include (i) a description of the individual's diagnosis; (ii) the type, amount, frequency, and duration of the CR/ICR items/services furnished; and (iii) the goals set for the individual under the plan. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

As specified at 42 CFR 410.49(f)(1), CR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the contractor under section 1862(a)(1)(A) of the Act. ICR sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

CR/ICR Program Setting Requirements:

CR/ICR services must be furnished in a physician's office or a hospital outpatient setting (for ICR, the hospital outpatient setting must provide ICR using an approved ICR program). All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items/services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision of physician office services as specified at 42 CFR 410.26, and for hospital outpatient services as specified at 42 CFR 410.27.

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ICR Program Approval Requirements:

All prospective ICR programs must be approved through the national coverage determination (NCD) process. To be approved as an ICR program, it must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients: (i) positively affected the progression of coronary heart disease, (ii) reduced the need for coronary bypass surgery, or, (iii) reduced the need for percutaneous coronary interventions.

An ICR program must also demonstrate through peer-reviewed, published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before CR services to after CR services: (i) low density lipoprotein, (ii) triglycerides, (iii) body mass index, (iv) systolic blood pressure, (v) diastolic blood pressure, and (vi) the need for cholesterol, blood pressure, and diabetes medications.

A list of approved ICR programs, identified through the NCD process, will be posted to the CMS Web site and listed in the Federal Register.

Once an ICR program is approved through the NCD process, all prospective ICR sites wishing to furnish ICR items/services via an approved ICR program may enroll with their local contractor to become an ICR program supplier using the designated forms as specified at 42 CFR 424.510, and report specialty code 31 to be identified as an enrolled ICR supplier. For purposes of appealing an adverse determination concerning site approval, an ICR site is considered a supplier (or prospective supplier) as defined in 42 CFR 498.2.

CR/ICR Program Physician Requirements:

Physicians responsible for CR/ICR programs are identified as medical directors who oversee or supervise the CR/ICR program at a particular site. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program. The medical director, as well as physicians acting as the supervising physician, must possess all of the following: (1) expertise in the management of individuals with cardiac pathophysiology, (2) cardiopulmonary training in basic life support or advanced cardiac life support, and (3) licensed to practice medicine in the state in which the CR/ICR program is offered. Direct physician supervision may be provided by a supervising physician or the medical director.

(See Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 140.2, for specific claims processing, coding, and billing requirements for CR/ICR program services.)

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240 - Chiropractic Services - General

(Rev. 1, 10-01-03)
B3-2250, B3-4118

The term “physician” under Part B includes a chiropractor who meets the specified qualifying requirements set forth in §30.5 but only for treatment by means of manual manipulation of the spine to correct a subluxation.

Effective for claims with dates of services on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation.

Implementation of the chiropractic benefit requires an appreciation of the differences between chiropractic theory and experience and traditional medicine due to fundamental differences regarding etiology and theories of the pathogenesis of disease. Judgments about the reasonableness of chiropractic treatment must be based on the application of chiropractic principles. So that Medicare beneficiaries receive equitable adjudication of claims based on such principles and are not deprived of the benefits intended by the law, carriers may use chiropractic consultation in carrier review of Medicare chiropractic claims.

Payment is based on the physician fee schedule and made to the beneficiary or, on assignment, to the chiropractor.

A. Verification of Chiropractor's Qualifications

Carriers must establish a reference file of chiropractors eligible for payment as physicians under the criteria in §30.1. They pay only chiropractors on file. Information needed to establish such files is furnished by the CMS RO.

The RO is notified by the appropriate State agency which chiropractors are licensed and whether each meets the national uniform standards.

240.1 - Coverage of Chiropractic Services

(Rev. 1, 10-01-03)
B3-2251

240.1.1 - Manual Manipulation

(Rev. 1, 10-01-03)
B3-2251.1

Coverage of chiropractic service is specifically limited to treatment by means of manual manipulation, i.e., by use of the hands. Additionally, manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

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No other diagnostic or therapeutic service furnished by a chiropractor or under the chiropractor's order is covered. This means that if a chiropractor orders, takes, or interprets an x-ray, or any other diagnostic test, the x-ray or other diagnostic test, can be used for claims processing purposes, but Medicare coverage and payment are not available for those services. This prohibition does not affect the coverage of x-rays or other diagnostic tests furnished by other practitioners under the program. For example, an x-ray or any diagnostic test taken for the purpose of determining or demonstrating the existence of a subluxation of the spine is a diagnostic x-ray test covered under §1861(s)(3) of the Act if ordered, taken, and interpreted by a physician who is a doctor of medicine or osteopathy.

Manual devices (i.e., those that are hand-held with the thrust of the force of the device being controlled manually) may be used by chiropractors in performing manual manipulation of the spine. However, no additional payment is available for use of the device, nor does Medicare recognize an extra charge for the device itself.

Effective for claims with dates of service on or after January 1, 2000, an x-ray is not required to demonstrate the subluxation. However, an x-ray may be used for this purpose if the chiropractor so chooses.

The word “correction” may be used in lieu of “treatment.” Also, a number of different terms composed of the following words may be used to describe manual manipulation as defined above:

- Spine or spinal adjustment by manual means;
- Spine or spinal manipulation;
- Manual adjustment; and
- Vertebral manipulation or adjustment.

In any case in which the term(s) used to describe the service performed suggests that it may not have been treatment by means of manual manipulation, the carrier analyst refers the claim for professional review and interpretation.

240.1.2 - Subluxation May Be Demonstrated by X-Ray or Physician’s Exam

(Rev. 1, 10-01-03)
B3-2251.2

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Subluxation is defined as a motion segment, in which alignment, movement integrity, and/or physiological function of the spine are altered although contact between joint surfaces remains intact.

A subluxation may be demonstrated by an x-ray or by physical examination, as described below.

1. Demonstrated by X-Ray

An x-ray may be used to document subluxation. The x-ray must have been taken at a time reasonably proximate to the initiation of a course of treatment. Unless more specific x-ray evidence is warranted, an x-ray is considered reasonably proximate if it was taken no more than 12 months prior to or 3 months following the initiation of a course of chiropractic treatment. In certain cases of chronic subluxation (e.g., scoliosis), an older x-ray may be accepted provided the beneficiary’s health record indicates the condition has existed longer than 12 months and there is a reasonable basis for concluding that the condition is permanent. A previous CT scan and/or MRI is acceptable evidence if a subluxation of the spine is demonstrated.

2. Demonstrated by Physical Examination

Evaluation of musculoskeletal/nervous system to identify:

Pain/tenderness evaluated in terms of location, quality, and intensity;

Asymmetry/misalignment identified on a sectional or segmental level;

Range of motion abnormality (changes in active, passive, and accessory joint movements resulting in an increase or a decrease of sectional or segmental mobility); and

Tissue, tone changes in the characteristics of contiguous, or associated soft tissues, including skin, fascia, muscle, and ligament.

To demonstrate a subluxation based on physical examination, two of the four criteria mentioned under "physical examination" are required, one of which must be asymmetry/misalignment or range of motion abnormality.

The history recorded in the patient record should include the following:

Symptoms causing patient to seek treatment;

Family history if relevant;

Past health history (general health, prior illness, injuries, or hospitalizations; medications; surgical history);

Mechanism of trauma;

Quality and character of symptoms/problem;

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Onset, duration, intensity, frequency, location and radiation of symptoms;

Aggravating or relieving factors; and

Prior interventions, treatments, medications, secondary complaints.

A. Documentation Requirements: Initial Visit

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History as stated above.

2. Description of the present illness including:

    Mechanism of trauma;

    Quality and character of symptoms/problem;

    Onset, duration, intensity, frequency, location, and radiation of symptoms;

Aggravating or relieving factors;

Prior interventions, treatments, medications, secondary complaints; and

Symptoms causing patient to seek treatment.

These symptoms must bear a direct relationship to the level of subluxation. The symptoms should refer to the spine (spondyle or vertebral), muscle (myo), bone (osseo or osteo), rib (costo or costal) and joint (arthro) and be reported as pain (algia), inflammation (itis), or as signs such as swelling, spasticity, etc. Vertebral pinching of spinal nerves may cause headaches, arm, shoulder, and hand problems as well as leg and foot pains and numbness. Rib and rib/chest pains are also recognized symptoms, but in general other symptoms must relate to the spine as such. The subluxation must be causal, i.e., the symptoms must be related to the level of the subluxation that has been cited. A statement on a claim that there is "pain" is insufficient. The location of pain must be described and whether the particular vertebra listed is capable of producing pain in the area determined.

3. Evaluation of musculoskeletal/nervous system through physical examination.

4. Diagnosis: The primary diagnosis must be subluxation, including the level of subluxation, either so stated or identified by a term descriptive of subluxation. Such terms may refer either to the condition of the spinal joint involved or to the direction of position assumed by the particular bone named.

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5. Treatment Plan: The treatment plan should include the following:

   Recommended level of care (duration and frequency of visits);

   Specific treatment goals; and

   Objective measures to evaluate treatment effectiveness.

6. Date of the initial treatment.

B. Documentation Requirements: Subsequent Visits

The following documentation requirements apply whether the subluxation is demonstrated by x-ray or by physical examination:

1. History

   Review of chief complaint;

   Changes since last visit;

System review if relevant.

2. Physical exam

   Exam of area of spine involved in diagnosis;

   Assessment of change in patient condition since last visit;

   Evaluation of treatment effectiveness.

3. Documentation of treatment given on day of visit.

240.1.3 - Necessity for Treatment

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)

The patient must have a significant health problem in the form of a neuromusculoskeletal condition necessitating treatment, and the manipulative services rendered must have a direct therapeutic relationship to the patient's condition and provide reasonable expectation of recovery or improvement of function. The patient must have a subluxation of the spine as demonstrated by x-ray or physical exam, as described above.

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Most spinal joint problems fall into the following categories:

- Acute subluxation-A patient's condition is considered acute when the patient is being treated for a new injury, identified by x-ray or physical exam as specified above. The result of chiropractic manipulation is expected to be an improvement in, or arrest of progression, of the patient's condition.

- Chronic subluxation-A patient's condition is considered chronic when it is not expected to significantly improve or be resolved with further treatment (as is the case with an acute condition), but where the continued therapy can be expected to result in some functional improvement. Once the clinical status has remained stable for a given condition, without expectation of additional objective clinical improvements, further manipulative treatment is considered maintenance therapy and is not covered.

For Medicare purposes, a chiropractor **must** place an AT modifier on a claim when providing active/corrective treatment to treat acute or chronic subluxation. However the presence of the AT modifier may not in all instances indicate that the service is reasonable and necessary. As always, contractors may deny if appropriate after medical review.

A. Maintenance Therapy

Maintenance therapy includes services that seek to prevent disease, promote health and prolong and enhance the quality of life, or maintain or prevent deterioration of a chronic condition. When further clinical improvement cannot reasonably be expected from continuous ongoing care, and the chiropractic treatment becomes supportive rather than corrective in nature, the treatment is then considered maintenance therapy. The AT modifier must not be placed on the claim when maintenance therapy has been provided. Claims without the AT modifier will be considered as maintenance therapy and denied. Chiropractors who give or receive from beneficiaries an ABN shall follow the instructions in Pub. 100-04, Medicare Claims Processing Manual, chapter 23, section 20.9.1.1 and include a GA (or in rare instances a GZ) modifier on the claim.

B. Contraindications

Dynamic thrust is the therapeutic force or maneuver delivered by the physician during manipulation in the anatomic region of involvement. A relative contraindication is a condition that adds significant risk of injury to the patient from dynamic thrust, but does not rule out the use of dynamic thrust. The doctor should discuss this risk with the patient and record this in the chart. The following are **relative contraindications** to dynamic thrust:

Articular hyper mobility and circumstances where the stability of the joint is uncertain;

Severe demineralization of bone;

Benign bone tumors (spine);

Bleeding disorders and anticoagulant therapy; and

Radiculopathy with progressive neurological signs.

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Dynamic thrust is absolutely contraindicated near the site of demonstrated subluxation and proposed manipulation in the following:

Acute arthropathies characterized by acute inflammation and ligamentous laxity and anatomic subluxation or dislocation; including acute rheumatoid arthritis and ankylosing spondylitis;

Acute fractures and dislocations or healed fractures and dislocations with signs of instability;

An unstable os odontoideum;

Malignancies that involve the vertebral column;

Infection of bones or joints of the vertebral column;

Signs and symptoms of myelopathy or cauda equina syndrome;

For cervical spinal manipulations, vertebrobasilar insufficiency syndrome; and

A significant major artery aneurysm near the proposed manipulation.

240.1.4 – Location of Subluxation

(Rev. 1, 10-01-03)
B3-2251.4

The precise level of the subluxation must be specified by the chiropractor to substantiate a claim for manipulation of the spine. This designation is made in relation to the part of the spine in which the subluxation is identified:

Area of Spine	Names of Vertebrae	Number of Vertebrae	Short Form or Other Name
Neck	Occiput	7	Occ, CO
	Cervical		C1 thru C7
	Atlas		C1
	Axis		C2
Back	Dorsal or	12	D1 thru D12
	Thoracic		T1 thru T12
	Costovertebral		R1 thru R12
	Costotransverse		R1 thru R12
Low Back	Lumbar	5	L1 thru L5
Pelvis	Iiii, r and 1		I, Si
Sacral	Sacrum, Coccyx		S, SC

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In addition to the vertebrae and pelvic bones listed, the Ilii (R and L) are included with the sacrum as an area where a condition may occur which would be appropriate for chiropractic manipulative treatment.

There are two ways in which the level of the subluxation may be specified.

The exact bones may be listed, for example: C5, C6, etc.

The area may suffice if it implies only certain bones such as: Occipito-atlantal (occiput and C1 (atlas)), lumbo-sacral (L5 and Sacrum), sacro-iliac (sacrum and ilium).

Following are some common examples of acceptable descriptive terms for the nature of the abnormalities:

Off-centered

Misalignment

Malpositioning

Spacing - abnormal, altered, decreased, increased

Incomplete dislocation

Rotation

Listhesis - antero, postero, retro, lateral, spondylo

Motion - limited, lost, restricted, flexion, extension, hyper mobility, hypomotility, aberrant

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Other terms may be used. If they are understood clearly to refer to bone or joint space or position (or motion) changes of vertebral elements, they are acceptable.

240.1.5 - Treatment Parameters

(Rev. 23, Issued: 10-08-04, Effective: 10-01-04, Implementation: 10-04-04)
B3-2251.5

The chiropractor should be afforded the opportunity to effect improvement or arrest or retard deterioration in such condition within a reasonable and generally predictable period of time. Acute subluxation (e.g., strains or sprains) problems may require as many as three months of treatment but some require very little treatment. In the first several days, treatment may be quite frequent but decreasing in frequency with time or as improvement is obtained.

Chronic spinal joint condition implies, of course, the condition has existed for a longer period of time and that, in all probability, the involved joints have already “set” and fibrotic tissue has developed. This condition may require a longer treatment time, but not with higher frequency.

Some chiropractors have been identified as using an “intensive care” concept of treatment. Under this approach multiple daily visits (as many as four or five in a single day) are given in the office or clinic and so-called room or ward fees are charged since the patient is confined to bed usually for the day. The room or ward fees are not covered and reimbursement under Medicare will be limited to not more than one treatment per day.

250 - Medical and Other Health Services Furnished to Inpatients of Hospitals and Skilled Nursing Facilities

(Rev. 1, 10-01-03)
B3-2255

There are several services which, when provided to a hospital or SNF inpatient, are covered under Part B, even though the patient has Part A coverage for the hospital or SNF stay. Those services are:

Physicians’ services (including the services of residents and interns in unapproved teaching programs);

Physician assistant services, furnished after December 31,1990;

Certified nurse-midwife services, as described in §180, furnished after December 31, 1990; and

Qualified clinical psychologist services, as defined in §160, furnished after December 31, 1990;

Screening mammography services;

Screening pap smears and pelvic exams;

Screening glaucoma services;

Influenza, pneumococcal pneumonia, and hepatitis B vaccines and their administrations;

Colorectal screening;

Bone mass measurements;

Diabetes self-management; and

Prostate screening;

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Because of the bundling requirement described in paragraph B, pneumococcal and hepatitis B vaccine services must be provided directly or arranged for by the hospital in

order to be covered when furnished to a hospital inpatient. The other services listed are not subject to bundling but, because they are excluded from the statutory definition of inpatient hospital services, may be covered only under Part B.

Payment may be made under Part B for the medical and other health services enumerated in paragraph C, but only where no payment can be made for such services under Part A. For example, payment may be made under Part B for the services in question where the beneficiary is an inpatient of a hospital or skilled nursing facility (SNF) and has exhausted his or her allowed days of inpatient coverage under Part A (or has elected not to use his or her lifetime reserve days). In the case of an inpatient of a SNF, Part B payment may be made if the patient is receiving Part A benefits for most of his or her care but the participating SNF does not furnish the services to its inpatients either directly or under arrangements (i.e., does not bill for services furnished to its inpatients by other suppliers).

A. Conditions for Part A Payment

In hospitals (including hospitals under the prospective payment system (PPS)) and SNFs, Part B payment may be made for the services listed in paragraph C if the services are reasonable and necessary and if:

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No Part A payment is made at all for the hospital or SNF stay because of patient exhaustion of benefit days before admission;

The admission was disapproved as not reasonable and necessary and limitation of liability payment was not made;

The patient was not otherwise eligible for or entitled to coverage under Part A (see the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §180); or

In the case of a hospital paid under the PPS, no Part A day outlier payment is made (for discharges before October 1997) for one or more outlier days due to patient exhaustion of benefit days after admission but before the case's arrival at outlier status or because outlier days are otherwise not covered and waiver of liability payment is not made. (Outlier days are days for which extra payment is made under PPS for long stay cases.)

Part B payment may be made for the medical and other health services listed in paragraph C when they are reasonable and necessary and furnished at any time during the stay if no Part A payment is made. However, if only day outlier payment is denied under Part A, Part B payment may be made for only the services furnished on the denied outlier days.

In non-PPS hospitals and in SNFs, Part B payment may be made for the indicated covered services delivered on any day for which Part A payment is denied (i.e., because of patient exhaustion of benefit days, the patient or services received were not at the

hospital level or SNF level of care, or the patient was not otherwise eligible for or entitled to payment under Part A).

B. Bundling of Services to Hospital Inpatients

In the case of a hospital inpatient, the services described in paragraph C are covered only if they are furnished by the hospital directly, or by another entity under arrangements made by the hospital. Only the hospital is allowed to bill for the services, and the bills must be submitted to the intermediary rather than to the carrier.

Certain services are exempt from the bundling requirement and may be billed directly to the carrier even when furnished to a hospital inpatient. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §170.)

C. Covered Part B Services When Part A Coverage is Not Available

The medical and other services covered under Part B when furnished to patients of hospitals and SNFs include the following:

Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests;

X-ray, radium, and radioactive isotope therapy including materials and services of technicians;

Surgical dressings, splints, casts, and other devices used for reduction of fractures and dislocations;

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Prosthetic devices (other than dental) which replace all or part of an internal body organ (including contiguous tissue), or all or part of the function of a permanently inoperative or malfunctioning internal body organ, including replacement or repairs of such devices;

Leg, arm, back, and neck braces, trusses, and artificial legs, arms, and eyes, including adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient's physical condition;

Outpatient physical therapy, outpatient occupational therapy, and outpatient speech-language pathology services; and

Ambulance services.

260 - Ambulatory Surgical Center Services

(Rev. 77; Issued: 08-29-07; Effective: 01-01-08; Implementation: 01-07-08)

Facility services furnished by ambulatory surgical centers (ASCs) in connection with certain surgical procedures are covered under Part B. To receive coverage of and

payment for its services under this provision, a facility must be certified as meeting the requirements for an ASC and enter into a written agreement with CMS. Medicare periodically updates the list of covered procedures and related payment amounts through release of regulations and change requests. The ASC must accept Medicare's payment for such procedures as payment in full with respect to those services defined as ASC facility services.

Where services are performed in an ASC, the physician and others who perform covered services may also be paid for his/her professional services; however, the "professional" rate is then adjusted since the ASC incurs the facility costs.

260.1 - Definition of Ambulatory Surgical Center (ASC)

(Rev. 104; Issued: 03-13-09; Effective Date: 04-01-09; Implementation Date: 04-06-09)

An ASC for purposes of this benefit is a distinct entity that operates exclusively for the purpose of furnishing outpatient surgical services to patients. It enters into an agreement with CMS to do so. An ASC is either independent (i.e., not a part of a provider of services or any other facility), or operated by a hospital (i.e., under the common ownership, licensure, or control of a hospital). To be covered as an ASC operated by a hospital, a facility elects to do so, and continues to be so covered unless CMS determines there is good cause to do otherwise. This provision is intended to prohibit such an entity from switching from one payment method to another to maximize its revenues (47 FR 34082, 34099, Aug. 5, 1982). For other general conditions and requirements, see 42 CFR 416.25-416.49. If the hospital based surgery center is certified as an ASC it is considered an ASC and is subject to rules for ASCs. Related survey requirements are published in the State Operations Manual, Pub. 100-07, Appendix L. Claims processing and payment requirements for ASCs are published in Pub. 100-04, the Medicare Claims Processing Manual, chapter 14.

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If a hospital based surgery center is not certified as an ASC it continues under the program as part of the hospital. In that case the applicable hospital outpatient payment rules apply. This is the outpatient prospective payment system (OPPS), for most hospitals, or may be provisions for hospitals excluded from OPPS. See Pub.100-04, the Medicare Claims Processing Manual, chapter 4, for billing and payment requirements for hospital outpatient services.

Indian Health Service (IHS) hospital outpatient departments are not certified as separate ASC entities. The ASC indication merely means that CMS approved them to bill for ASC services and be paid based on the ASC rates for services on the ASC list. In order to bill for ASC services, the hospital outpatient department must meet the conditions of participation for hospitals defined at 42 CFR, Part 482. See Pub. 100-04, the Medicare Claims Processing Manual, chapter 19, sections 40.2.1, and 80.9 for more information on IHS hospital outpatient departments billing for ASC services.

260.2 - Ambulatory Surgical Center Services

(Rev. 77; Issued: 08-29-07; Effective: 01-01-08; Implementation: 01-07-08)

The ASC facility services are services furnished in an ASC in connection with a covered surgical procedure that are otherwise covered if furnished on an inpatient or outpatient basis in a hospital in connection with that procedure. Not included in the definition of facility services are medical and other health services, even though furnished within the ASC, which are covered under other portions of the Medicare program, or not furnished in connection with covered surgical procedures. This distinction between covered ASC facility services and services which are not covered ASC facility services is important, since the facility payment rate includes only the covered ASC facility services. Services, which are not covered ASC facility services such as physicians' services and prosthetic devices other than intraocular lenses (IOLs), may be covered and billable under other Medicare provisions.

Since there is no uniformity among ASCs as to what items and services they include in their facility fee or charge, the Medicare definition of covered facility services is both inclusive and exclusive. The regulations specify what are and are not facility services. Facility services are items and services furnished in connection with listed covered procedures, which are covered if furnished in a hospital operating suite or hospital outpatient department in connection with such procedures. These do not include physicians' services, or medical and other health services for which payment may be made under other Medicare provisions (e.g., services of an independent laboratory located on the same site as the ASC, anesthetist professional services, non-implantable DME).

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Examples of covered ASC facility services include:

Nursing Services, Services of Technical Personnel, and Other Related Services

These include all services in connection with covered procedures furnished by nurses and technical personnel who are employees of the ASC. In addition to the nursing staff, this category includes orderlies, technical personnel, and others involved in patient care;

Use by the Patient of the ASC's Facilities

This category includes operating and recovery rooms, patient preparation areas, waiting rooms, and other areas used by the patient or offered for use by the patient's relatives in connection with surgical services; and

Drugs, Biologicals, Surgical Dressings, Supplies, Splints, Casts, Appliances, and Equipment

This category includes all supplies and equipment commonly furnished by the ASC in connection with surgical procedures. See below for certain exceptions. Drugs and biologicals are limited to those that cannot be self-administered. (See §60.)

Coverage policy for surgical dressings is similar to that followed under Part B. Under Part B, coverage for surgical dressings is limited to primary dressings; i.e., therapeutic and protective coverings applied directly to lesions on the skin or on openings to the skin required as the result of surgical procedures. (Items such as Ace bandages, elastic stockings and support hose, Spence boots and other foot coverings, leotards, knee supports, surgical leggings, gauntlets, and pressure garments for the arms and hands are generally used as secondary coverings and therefore are not covered as surgical dressings.) Surgical dressings usually are applied first by a physician and are covered as "incident to" a physician's service in a physician's office setting. In the ASC setting, such dressings are included in the facility's services.

However, others may reapply surgical dressings later, including the patient or a member of the patient's family. When the patient on a physician's order obtains surgical dressings from a supplier, e.g., a drugstore, the surgical dressing is covered under Part B. The same policy applies in the case of dressings obtained by the patient on a physician's order following surgery in an ASC; the dressings are covered and paid as a Part B service by the local Part B contractor, included in the definition of facility services.

Similarly, "other supplies, splints, and casts" include only those furnished by the ASC at the time of the surgery. Additional covered supplies and materials furnished later are generally furnished as "incident to" a physician's service, not as an ASC facility service. The term "supplies" includes those required for both the patient and ASC personnel, e.g., gowns, masks, drapes, hoses, and scalpels, whether disposable or reusable.

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Diagnostic or Therapeutic Items and Services

These are items and services furnished by ASC staff in connection with covered surgical procedures. With respect to diagnostic tests, many ASCs perform simple tests just before surgery, primarily urinalysis and blood hemoglobin or hematocrit, which are generally included in their facility charges. To the extent that such simple tests are included in the ASC's facility charges, they are considered facility services. However, under the Medicare program, diagnostic tests are not covered in laboratories independent of a physician's office, rural health clinic, or hospital unless the laboratories meet the regulatory requirements for the conditions for coverage of services of independent laboratories. (See 42CFR416.49.) Therefore, diagnostic tests performed by the ASC other than those generally included in the facility's charge are not covered under Part B as such and are not billed to the carrier as diagnostic tests. If the ASC has its laboratory certified as meeting the regulatory conditions, then the laboratory itself bills the contractor (or the beneficiary) for the tests performed.

The ASC may make arrangements with an independent laboratory or other laboratory, such as a hospital laboratory, to perform diagnostic tests it requires prior to surgery. In general, however, the necessary laboratory tests are done outside the ASC prior to scheduling of surgery, since the test results often determine whether the beneficiary should even have the surgery done on an outpatient basis in the first place.

Administrative, Recordkeeping, and Housekeeping Items and Services

These include the general administrative functions necessary to run the facility e.g., scheduling, cleaning, utilities, and rent.

Blood, Blood Plasma, Platelets, etc., Except Those to Which Blood Deductible Applies

While covered procedures are limited to those not expected to result in extensive loss of blood, in some cases, blood or blood products are required. Usually the blood deductible results in no expenses for blood or blood products being included under this provision. However, where there is a need for blood or blood products beyond the deductible, they are considered ASC facility services and no separate charge is permitted to the beneficiary or the program.

Materials for Anesthesia

These include the anesthetic itself, and any materials, whether disposable or reusable, necessary for its administration.

Intraocular Lenses (IOLs)

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Effective for services furnished on or after March 12, 1990, ASC facility services include intraocular lenses approved by the Food and Drug Administration (FDA) for insertion during or subsequent to cataract surgery.

FDA has classified IOLs into the following four categories, any of which are included:

Anterior chamber angle fixation lenses;
Iris fixation lenses;
Irido-capsular fixation lenses; and
Posterior chamber lenses.

While FDA has approved many IOLs, it still considers some IOLs investigational. The fact that they are covered under Medicare is an exception to the general policy not to cover experimental or investigational items or services. The exception is made because the Congress, recognizing the widespread use of IOLs, directed the FDA to study them without interfering with availability to patients.

The carrier determines whether the item or service falls into the categories described in the following section. If it determines the item or service does fall into one of those categories, it makes payment following the applicable rules for such items and services found elsewhere in this chapter. If the item or service does not fall into one of the categories described, the carrier denies the claim.

Covered ASC surgical procedures are those surgical procedures that are identified by CMS on an annually updated ASC listing. Some surgical procedures covered by Medicare are not on the ASC list of covered surgical procedures.

Under the revised ASC payment system, Medicare makes facility payments to ASCs only for the specific ASC covered surgical procedures and covered ancillary services that are provided integral to a covered ASC surgical procedure.

See chapter 14, section 10 of Pub. 100-04, Medicare Claims Processing Manual for examples of covered ASC services for which payment is included in the ASC payment for a covered surgical procedure under 42CFR416.65.

There is a payment adjustment for insertion of an IOL approved as belonging to a class of NTIOLs, for the 5-year period of time established for that class, as set forth at 42CFR416.200.

260.3 - Services Furnished in ASCs Which are Not ASC Facility Services

(Rev. 1, 10-01-03)
B3-2265.3

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A single payment is made to an ASC that encompasses all "facility services" furnished by the ASC in connection with a covered procedure. However, a number of items and services covered under Medicare may be furnished in an ASC which are not considered facility services, and which the ASC payment does not include. These non-ASC services are covered and paid for under the applicable provisions of Part B. In addition, the ASC may be part of a medical complex that includes other entities, such as an independent laboratory, supplier of durable medical equipment, or a physician's office, which are covered as separate entities under Part B. In general, an item or service separately covered under Medicare is not considered an ASC service. Examples of services payable in addition to ASC services are found in §260.4.

260.4 - Coverage of Services in ASCs, Which are Not ASC Services

(Rev. 77; Issued: 08-29-07; Effective: 01-01-08; Implementation: 01-07-08)

Physicians' Services

This category includes most covered services performed in ASCs, which are not considered ASC facility services. Physicians' services were covered before coverage of ASC services, and the ASC amendment did not change this. Consequently, physicians who perform covered services in ASCs receive payment under the existing Part B system. Physicians' services include the services of anesthesiologists administering or supervising the administration of anesthesia to beneficiaries in ASC's and the beneficiaries' recovery from the anesthesia. The term physicians' services also includes any routine pre- or post-operative services, such as office visits, consultations, diagnostic tests, removal of stitches, changing of dressings, and other services that the individual

physician usually includes in the fee for a given surgical procedure.. The contractor applies the same criteria, limits and understandings to physicians' services for procedures furnished in the ASC that are applied to the procedures furnished by the same physicians on an inpatient hospital basis.

The Sale, Lease, or Rental of Durable Medical Equipment (DME) to ASC Patients for Use in Their Homes

Non-implantable Durable Medical Equipment (DME) - If the ASC furnishes items of non-implantable DME to beneficiaries, it is treated as a DME supplier, and all the rules and conditions ordinarily applicable to DME are applicable, including obtaining a supplier number and billing the DME MAC where applicable.

Prosthetic Devices

Prosthetic devices, other than intraocular lenses (IOLs), whether implanted, inserted, or otherwise applied by covered surgical procedures, are covered, but are not included in the ASC facility payment amount. However, §4063(b) of P.L. 100-203 amended §1833 (i)(2)(A) of the Act to mandate that payment for an intraocular lens (IOL) inserted during or subsequent to cataract surgery in an ASC be included in the facility payment rate. This bundling of the payment for an IOL with the facility fee is effective for services furnished on or after March 12, 1990. More information on coverage of prosthetic devices may be found in §120. Further information on the coverage of IOLs may be found in §260.2.

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Non-Implantable Prosthetic Devices - If the ASC furnishes non-implantable prosthetic devices to beneficiaries, the ASC is treated as a supplier, and all the rules and conditions ordinarily applicable to suppliers are applicable, including obtaining a supplier number and billing the DME MAC where applicable.

Ambulance Services

If the ASC furnishes ambulance services, they are covered as ambulance services pursuant to the terms and conditions of the Medicare Benefit Policy Manual, Chapter 10, "Ambulance Services," §§10. The facility may obtain approval as an ambulance supplier to bill covered ambulance services.

Leg, Arm, Back, and Neck Braces

These items of equipment, like prosthetic devices, are covered under Part B, but are not included in the ASC facility payment amount. Coverage of these items is described in §130. If the ASC furnishes these to beneficiaries, it is treated as a supplier, and all the rules and conditions ordinarily applicable to suppliers are applicable, including obtaining a supplier number and billing the DME MAC where applicable.

Artificial Legs, Arms, and Eyes

Like prosthetic devices and braces, this equipment is not considered part of an ASC facility service and so is not included in the ASC facility payment rate. Information regarding the coverage of these items is set out in §130. If the ASC furnishes these items to beneficiaries, it is treated as a supplier, and all the rules and conditions ordinarily applicable to suppliers are applicable, including obtaining a supplier number and billing the DME MAC where applicable.

Services of Independent Laboratory

As noted in §260.2, only a very limited number and type of diagnostic tests are considered ASC facility services and included in the ASC facility payment rate. In most cases, diagnostic tests performed directly by an ASC are not considered ASC facility services and are not covered under Medicare. Section 1861(s) of the Act limits coverage of diagnostic lab tests in facilities other than physicians' offices, rural health clinics, or hospitals to facilities that meet the statutory definition of an independent laboratory. (See §§80.1 for a description of independent laboratories and covered services.) In order to bill for diagnostic tests as a laboratory, an ASC's laboratory must be CLIA certified and enrolled with the contactor as a laboratory and the certified clinical laboratory must bill for the services provided to the beneficiary in the ASC. Otherwise, the ASC makes arrangements with a covered laboratory or laboratories for laboratory services, as provided in 42 CFR 416.49. If the ASC has a certified independent laboratory, the laboratory itself bills the carrier, pursuant to §§80.

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260.5 - List of Covered Ambulatory Surgical Center Procedures
(Rev. 77; Issued: 08-29-07; Effective: 01-01-08; Implementation: 01-07-08)

The law ties coverage of ambulatory surgical center (ASC) services under Part B to specified surgical procedures, which are contained in a list revised and published periodically by CMS. Groupings and related prices are also published periodically. These are published in the Federal Register and on the CMS Web site.

Beginning January 1, 2008, under the revised ASC payment system, CMS will update the list of covered surgical procedures, relative payment weights and national unadjusted payment rates, annually. The updates will be proposed and finalized in the Federal Register concurrent with updates to the hospital outpatient prospective payment system.

260.5.1 - Nature and Applicability of ASC List
(Rev. 77; Issued: 08-29-07; Effective: 01-01-08; Implementation: 01-07-08)

The ASC list of covered surgical procedures indicates procedures that are covered and may be paid for if performed in the ASC setting. There is no requirement that the covered surgical procedures be performed only in ASCs. The decision regarding the most appropriate care setting for a given surgical procedure is made by the physician based on the beneficiary's individual clinical needs and preferences. Also, all the general coverage rules requiring that any procedure be reasonable and necessary for the

beneficiary are applicable to ASC services in the same manner as all other covered services.

260.5.2 - Nomenclature and Organization of the List

(Rev. 77; Issued: 08-29-07; Effective: 01-01-08; Implementation: 01-07-08)

The listed procedures are all considered "surgical procedures" for coverage purposes under the ASC provision, regardless of the specific use to which the procedure is put. For example, many of the "oscopy" procedures listed - bronchoscopy, laryngoscopy, etc., may be employed for either diagnostic or therapeutic purposes, or both at the same time, such as when the "oscopy" permits both detection and removal of a polyp. Those procedures are considered "surgical procedures" within the context of the ASC provision. Also, surgical procedures are commonly thought of as those involving an incision of some type, whether done with a scalpel or (more recently) a laser, followed by removal or repair of an organ or other tissue. In recent years, the development of fiber optics technology, together with new surgical instruments utilizing that technology, has resulted in surgical procedures that, while invasive and manipulative, do not require incisions. Instead, the procedures are performed without an incision through various body openings. Those procedures, some of which include the "oscopy" procedures mentioned above, are also considered surgical procedures for purposes of the ASC provision, and several are included in the list of covered procedures.

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Beginning January 1, 2008, the ASC list of covered surgical procedures is comprised of surgical procedures that CMS determines do not pose a significant safety risk and are not expected to require an overnight stay following the surgical procedure.

Surgical procedures are defined as Category I CPT codes within the surgical range of CPT codes, 10000 through 69999. Also considered to be included within that code range are Level II HCPCS and Category III CPT codes that crosswalk to or are clinically similar to the Category I CPT codes in the range.

The surgical codes that are included on the ASC list of covered surgical procedures are those that have been determined to pose no significant safety risk to Medicare beneficiaries when furnished in ASCs and that are not expected to require active medical monitoring at midnight of the day on which the surgical procedure is performed (overnight stay).

Procedures that are included on the inpatient list used under Medicare's hospital outpatient prospective payment system and procedures that can only be reported by using an unlisted Category I CPT code are deemed to pose significant safety risk to beneficiaries in ASCs and are not eligible for designation and coverage as covered surgical procedures.

260.5.3 - Rebundling of CPT Codes

(Rev. 1, 10-01-03)
B3-2266.3

Instructions regarding the Correct Coding Initiative apply to coverage of ASC facility services.

270 - Telehealth Services

(Rev. 140, Issued: 02-28-11, Effective: 01-01-11, Implementation: 01-03-11 A/B MACs, Carriers/04-04-11 A/B MACs, FIs)

Background

Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) - Revision of Medicare Reimbursement for Telehealth Services amended §1834 of the Act to provide for an expansion of Medicare payment for telehealth services.

Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system. E ligible geographic areas include rural health professional shortage areas (HPSA) and counties not classified as a metropolitan statistical area (MSA). Additionally, Federal telemedicine demonstration projects as of December 31, 2000, may serve as the originating site regardless of geographic location.

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An interactive telecommunications system is required as a condition of payment; however, BIPA does allow the use of asynchronous "store and forward" technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. BIPA does not require that a practitioner present the patient for interactive telehealth services.

With regard to payment amount, BIPA specified that payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner is physically located at time of telemedicine encounter) is equal to what would have been paid without the use of telemedicine. Distant site practitioners include only a physician as described in §1861(r) of the Act and a medical practitioner as described in §1842(b)(18)(C) of the Act. BIPA also expanded payment under Medicare to include a $20 originating site facility fee (location of beneficiary).

Previously, the Balanced Budget Act of 1997 (BBA) limited the scope of Medicare telehealth coverage to consultation services and the implementing regulation prohibited the use of an asynchronous 'store and forward' telecommunications system. The BBA of 1997 also required the professional fee to be shared between the referring and consulting practitioners, and prohibited Medicare payment for facility fees and line charges associated with the telemedicine encounter.

The BIPA required that Medicare Part B (Supplementary Medical Insurance) pay for this expansion of telehealth services beginning with services furnished on October 1, 2001.

Section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended §1834(m) of the Act to add certain entities as originating sites for payment of telehealth services. Effective for services furnished on or after January 1, 2009, eligible originating sites include a hospital-based or critical access hospital-based renal dialysis center (including satellites); a skilled nursing facility (as defined in §1819(a) of the Act); and a community mental health center (as defined in §1861(ff)(3)(B) of the Act). MIPPA also amended§1888(e)(2)(A)(ii) of the Act to exclude telehealth services furnished under §1834(m)(4)(C)(ii)(VII) from the consolidated billing provisions of the skilled nursing facility prospective payment system (SNF PPS).

NOTE: MIPPA did not add independent renal dialysis facilities as originating sites for payment of telehealth services.

The telehealth provisions authorized by §1834(m) of the Act are implemented in 42 CFR 410.78 and 414.65.

270.1 - Eligibility Criteria

(Rev. 97, Issued: 11-14-08, Effective: 01-01-09, Implementation: 01-05-09)

Beneficiaries are eligible for telehealth services **only** if they are presented from an originating site located either in a rural HPSA or in a county outside of an MSA.

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Entities participating in a Federal telemedicine demonstration project that were approved by or were receiving funding from the Secretary of Health and Human Services as of December 31, 2000, qualify as originating sites regardless of geographic location. Such entities are not required to be in a rural HPSA or non-MSA.

An originating site is the location of an eligible Medicare beneficiary at the time the service being furnished via telecommunications system occurs. Originating sites authorized by law are listed below.

The office of a physician or practitioner;
A hospital;
A critical access hospital (CAH);
A rural health clinic (RHC);
A federally qualified health center (FQHC);
A hospital-based or critical access hospital-based renal dialysis center (including satellites) (Effective January 1, 2009.);
A skilled nursing facility (SNF) (Effective January 1, 2009.);
A community mental health center (CMHC) (Effective January 1, 2009.).

NOTE: Independent renal dialysis facilities are not eligible originating sites.

270.2 – List of Medicare Telehealth Services

(Rev. 151, Issued: 11-18-11, Effective: 01-01-12, Implementation: 01-03-12)

The use of a telecommunications system may substitute for an in-person encounter for professional consultations, office visits, office psychiatry services, and a limited number of other physician fee schedule (PFS) services. These services are listed below.

Consultations (Effective October 1, 2001- December 31, 2009)

Telehealth consultations, emergency department or initial inpatient (Effective January 1, 2010)

Follow-up inpatient telehealth consultations (Effective January 1, 2009)

Office or other outpatient visits

Subsequent hospital care services (with the limitation of one telehealth visit every 3 days) (Effective January 1, 2011)

Subsequent nursing facility care services (with the limitation of one telehealth visit every 30 days) (Effective January 1, 2011)

Individual psychotherapy

Pharmacologic management

Psychiatric diagnostic interview examination (Effective March 1, 2003)

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End stage renal disease related services (Effective January 1, 2005)

Individual and group medical nutrition therapy (Individual effective January 1, 2006; group effective January 1, 2011)

Neurobehavioral status exam (Effective January 1, 2008)

Individual and group health and behavior assessment and intervention (Individual effective January 1, 2010; group effective January 1, 2011)

Individual and group kidney disease education (KDE) services (Effective January 1, 2011)

Individual and group diabetes self-management training (DSMT) services (with a minimum of 1 hour of in-person instruction to be furnished in the initial year training period to ensure effective injection training) (Effective January 1, 2011)

Smoking Cessation Services (Effective January 1, 2012)

NOTE: Beginning January 1, 2010, CMS eliminated the use of all consultation codes, except for inpatient telehealth consultation G-codes. CMS no longer recognizes office/outpatient or inpatient consultation CPT codes for payment of office/outpatient or inpatient visits. Instead, physicians and practitioners are instructed to bill a new or established patient office/outpatient visit CPT code or appropriate hospital or nursing facility care code, as appropriate to the particular patient, for all office/outpatient or inpatient visits. For detailed instructions regarding reporting these and other telehealth services, see Pub. 100-04, Medicare Claims Processing Manual, chapter 12, section 190.3.

The conditions of payment for Medicare telehealth services, including qualifying originating sites and the types of telecommunications systems recognized by Medicare, are subject to the provisions of 42 CFR 410.78. Payment for these services is subject to the provisions of 42 CFR 414.65.

270.3 – Conditions of Payment
(Rev. 1, 10-01-03)

Furnished by CMS

For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit.

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Exception to the Interactive Telecommunications Requirement

In the case of Federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telemedicine when asynchronous "store and forward technology," in single or multimedia formats, is used as a substitute for an interactive telecommunications system. The originating site and distant site practitioner must be included within the definition of the demonstration program.

For the purposes of this instruction, store and forward means the asynchronous transmission of medical information to be reviewed at a later time by a physician or practitioner at the distant site. A patient's medical information may include but not limited to, video clips, still images, x-rays, MRIs, EKGs and EEGs, laboratory results, audio clips, and text. The physician or practitioner at the distant site reviews the case without the patient being present. Store and forward substitutes for an interactive encounter with the patient present; the patient is not present in real-time.

NOTE: Asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis or a treatment

plan. Dermatological photographs, e.g., photographs of a skin lesion, may be considered to meet the requirement of a single media format under this instruction.

Telepresenters: A medical professional is not required to present the beneficiary to the physician or practitioner at the distant site unless medically necessary. The decision of medical necessity will be made by the physician or practitioner located at the distant site.

270.4 – Payment – Physician/Practitioner at a Distant Site

(Rev. 140, Issued: 02-28-11, Effective: 01-01-11, Implementation: 01-03-11 A/B MACs, Carriers/04-04-11 A/B MACs, FIs)

The term "distant site" means the site where the physician or practitioner providing the professional service is located at the time the service is provided via a telecommunications system.

The payment amount for the professional service provided via a telecommunications system by the physician or practitioner at the distant site is equal to the current physician fee schedule amount for the service. Payment for telehealth services (see section 270.2 of this chapter) should be made at the same amount as when these services are furnished without the use of a telecommunications system. For Medicare payment to occur, the service must be within a practitioner's scope of practice under State law. The beneficiary is responsible for any unmet deductible amount and applicable coinsurance.

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Medicare Practitioners Who May Receive Payment at the Distant Site (i.e., at a Site Other Than Where the Beneficiary is Located)

As a condition of Medicare Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under State law. When the physician or practitioner at the distant site is licensed under State law to provide a covered telehealth service (see section 270.2 of this chapter) then he or she may bill for and receive payment for this service when delivered via a telecommunications system.

Medicare practitioners who may bill for a covered telehealth service are listed below (subject to State law):

Physician;
Nurse practitioner;
Physician assistant;
Nurse midwife;
Clinical nurse specialist;
Clinical psychologist;
Clinical social worker; and
Registered dietitian or nutrition professional.

* Clinical psychologists and clinical social workers cannot bill for psychotherapy services that include medical evaluation and management services under Medicare. These practitioners may not bill or receive payment for the following CPT codes: 90805, 90807, and 90809.

270.4.1 – Payment for ESRD-Related Services as a Telehealth Service
(Rev. 97, Issued: 11-14-08, Effective: 01-01-09, Implementation: 01-05-09)

The ESRD-related services included in the monthly capitation payment (MCP) with 2 or 3 visits per month and ESRD-related services with 4 or more visits per month may be paid as Medicare telehealth services. However, at least 1 visit must be furnished face-to-face "hands on" to examine the vascular access site by a physician, clinical nurse specialist, nurse practitioner, or physicians assistant. An interactive audio and video telecommunications system may be used for providing additional visits required under the 2-to-3 visit MCP and the 4-or-more visit MCP. The medical record must indicate that at least one of the visits was furnished face-to-face "hands on" by a physician, clinical nurse specialist, nurse practitioner, or physician assistant.

The MCP physician, for example, the physician or practitioner who is responsible for the complete monthly assessment of the patient and establishes the patient's plan of care, may use other physicians and practitioners to furnish ESRD-related visits through an interactive audio and video telecommunications system. The non-MCP physician or practitioner must have a relationship with the billing physician or practitioner such as a partner, employees of the same group practice or an employee of the MCP physician, for example, the non MCP physician or practitioner is either a W-2 employee or 1099 independent contractor. However, the physician or practitioner who is responsible for the complete monthly assessment and establishes the ESRD beneficiary's plan of care should bill for the MCP in any given month.

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Clinical Criteria

The visit including a clinical examination of the vascular access site must be conducted face-to-face "hands on" by a physician, clinical nurse specialist, nurse practitioner or physician's assistant. For additional visits, the physician or practitioner at the distant site is required, at a minimum, to use an interactive audio and video telecommunications system that allows the physician or practitioner to provide medical management services for a maintenance dialysis beneficiary. For example, an ESRD-related visit conducted via telecommunications system must permit the physician or practitioner at the distant site to perform an assessment of whether the dialysis is working effectively and whether the patient is tolerating the procedure well (physiologically and psychologically). During this assessment, the physician or practitioner at the distant site must be able to determine whether alteration in any aspect of the beneficiary's prescription is indicated, due to such changes as the estimate of the patient's dry weight.

270.4.2 – Payment for Subsequent Hospital Care Services and Subsequent Nursing Facility Care Services as Telehealth Services

(Rev. 140, Issued: 02-28-11, Effective: 01-01-11, Implementation: 01-03-11 A/B MACs, Carriers/04-04-11 A/B MACs, FIs)

Subsequent hospital care services are limited to one telehealth visit every 3 days. The frequency limit of the benefit is not intended to apply to consulting physicians or practitioners, who should continue to report initial or follow-up inpatient telehealth consultations using the applicable HCPCS G-codes.

Similarly, subsequent nursing facility care services are limited to one telehealth visit every 30 days. Furthermore, subsequent nursing facility care services reported for a Federally-mandated periodic visit under 42 CFR 483.40(c) may not be furnished through telehealth. The frequency limit of the benefit is not intended to apply to consulting physicians or practitioners, who should continue to report initial or follow-up inpatient telehealth consultations using the applicable HCPCS G-codes.

Inpatient telehealth consultations are furnished to beneficiaries in hospitals or skilled nursing facilities via telehealth at the request of the physician of record, the attending physician, or another appropriate source. The physician or practitioner who furnishes the initial inpatient consultation via telehealth cannot be the physician or practitioner of record or the attending physician or practitioner, and the initial inpatient telehealth consultation would be distinct from the care provided by the physician or practitioner of record or the attending physician or practitioner. Counseling and coordination of care with other providers or agencies is included as well, consistent with the nature of the problem(s) and the patient's needs. Initial and follow-up inpatient telehealth consultations are subject to the criteria for inpatient telehealth consultation services, as described in Pub. 100-04, Medicare Claims Processing Manual, chapter 12, section 190.3.

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270.4.3 – Payment for Diabetes Self-Management Training (DSMT) as a Telehealth Service

(Rev. 140, Issued: 02-28-11, Effective: 01-01-11, Implementation: 01-03-11 A/B MACs, Carriers/04-04-11 A/B MACs, FIs)

Individual and group DSMT services may be paid as a Medicare telehealth service; however, at least 1 hour of the 10 hour benefit in the year following the initial DSMT service must be furnished in-person to allow for effective injection training. The injection training may be furnished through either individual or group DSMT services. By reporting the –GT or –GQ modifier with HCPCS code GO108 (Diabetes outpatient self-management training services, individual, per 30 minutes) or G0109 Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes), the distant site practitioner certifies that the beneficiary has received or will receive 1 hour of in-person DSMT services for purposes of injection training during the year following the initial DSMT service.

As specified in 42 CFR 410.141(e) and stated in section 300.2 of this chapter, individual DSMT services may be furnished by a physician, individual, or entity that furnishes other

services for which direct Medicare payment may be made and that submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS. However, consistent with the statutory requirements of section 1834(m)(1) of the Act, as provided in 42 CFR 410.78(b)(1) and (b)(2) and stated in section 270.4 of this chapter**,** Medicare telehealth services, including individual DSMT services furnished as a telehealth service, could only be furnished by a licensed physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), certified nurse-midwife (CNM), clinical psychologist, clinical social worker, or registered dietitian or nutrition professional.

270.5 - Originating Site Facility Fee Payment Methodology

(Rev. 151, Issued: 11-18-11, Effective: 01-01-12, Implementation: 01-03-12)

The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. For asynchronous, store and forward telecommunications technologies, an originating site is only a Federal telemedicine demonstration program conducted in Alaska or Hawaii. The originating site facility fee is a separately billable Part B payment. The contractor pays it outside of other payment methodologies. This fee is subject to post payment verification.

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For telehealth services furnished from October 1, 2001, through December 31, 2002, the originating site facility fee is the lesser of $20 or the actual charge. For services furnished on or after January 1 of each subsequent year, the originating site facility fee is updated by the Medicare Economic Index. The updated fee is included in the Medicare Physician Fee Schedule (MPFS) Final Rule, which is published by November 1 prior to the start of the calendar year for which it is effective. The updated fee for each calendar year is also issued annually in a Recurring Update Notification instruction for January of each year.

The originating site facility fee is a separately billable Part B payment. The payment amount to the originating site is the lesser of 80 percent of the actual charge or 80 percent of the originating site facility fee, except CAHs. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance.

The originating site facility fee payment methodology for each type of facility is clarified below:

When the originating site is a hospital outpatient department, payment for the originating site facility fee must be made as described above and not under the outpatient prospective payment system (OPPS). Payment is not based on the OPPS payment methodology.

For hospital inpatients, payment for the originating site facility fee must be made outside the diagnostic related group (DRG) payment since this is a Part B benefit, similar to other services paid separately from the DRG payment.

When the originating site is a critical access hospital, contractors make payment separately from the cost-based reimbursement methodology. For CAH's, the payment amount is 80 percent of the originating site facility fee.

The originating site facility fee for telehealth services is not an FQHC and RHC service. When an FQHC or RHC serves as the originating site, the originating site facility fee must be paid separately from the center or clinic all-inclusive rate.

When the originating site is a physician's or practitioner's office, the payment amount, in accordance with the law, is the lesser of 80 percent of the actual charge or 80 percent of the originating site facility fee regardless of geographic location. The geographic cost index (GPCI) should not be applied to the originating site facility fee. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the MPFS.

When a hospital-based or critical access hospital-based renal dialysis center (or their satellites) serves as the originating site, the originating site facility fee is covered in addition to any composite rate or MCP amount.

The originating site facility fee is outside the SNF prospective payment system bundle and, as such, is not subject to SNF consolidated billing. The originating site facility fee is a separately billable Part B payment.

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When a CMHC serves as an originating site, the originating site facility fee is not a partial hospitalization service. The originating site facility fee does not count towards the number of services used to determine payment for partial hospitalization services. The originating site facility fee is not bundled in the per diem payment for partial hospitalization. The originating site facility fee is a separately billable Part B payment.

270.5.1 - Originating Site Facility Fee Payment (ESRD-Related Services)

(Rev. 105, Issued: 04-24-09; Effective: 01-01-09; Implementation: 05-26-09)

With regard to ESRD-related services included in the MCP, the originating site facility fee payment may be made for each visit furnished through an interactive telecommunications system. When the physician or practitioner at the distant site furnishes an ESRD-related patient visit(s) included in the MCP through an interactive telecommunications system, the originating site facility may bill for a telehealth facility fee.

EXAMPLE: A 70 year old ESRD beneficiary receives 2 ESRD-related visits through an interactive telecommunications system and the required face-to-face visit (to examine the vascular access site) during the month of November. In this scenario the originating site should bill for two originating site facility fees as described by HCPCS code Q3014 and the MCP physician at the distant site should bill for ESRD-related services with 2 to 3 visits as a telehealth service with the "GT" modifier.

For more information on telehealth claims processing see Pub. 100-04, chapter 12, section 190 (Medicare telehealth claims processing).

280 – Preventive and Screening Services

(Rev. 93; Issued: 07-25-08; Effective Date: 04-28-08; Implementation Date: 08-25-08)

See section 50.4.4.2 for coverage requirements for PPV, hepatitis B vaccine, and Influenza Virus Vaccine.

See Pub. 100-04, Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for coverage requirements for the following:

- §40 for screening pelvic examinations,
- §50 for prostate cancer screening test and procedures,
- §60 for colorectal cancer screening, and,
- §70.4 for glaucoma screening.

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280.1 – Glaucoma Screening

(Rev. 48, Issued: 03-24-06; Effective: 01-01-06; Implementation: 04-03-06)

A. Conditions of Coverage

The regulations implementing the Benefits Improvements and Protection Act of 2000, §102, provide for annual coverage for glaucoma screening for beneficiaries in the following high risk categories:

- Individuals with diabetes mellitus;
- Individuals with a family history of glaucoma; or
- African-Americans age 50 and over.

In addition, beginning with dates of service on or after January 1, 2006, 42 CFR 410.23(a)(2), revised, the definition of an eligible beneficiary in a high-risk category is expanded to include:

- Hispanic-Americans age 65 and over.

Medicare will pay for glaucoma screening examinations where they are furnished by or under the direct supervision in the office setting of an ophthalmologist or optometrist, who is legally authorized to perform the services under State law.

Screening for glaucoma is defined to include:

- A dilated eye examination with an intraocular pressure measurement; and
- A direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

Payment may be made for a glaucoma screening examination that is performed on an eligible beneficiary after at least 11 months have passed following the month in which the last covered glaucoma screening examination was performed.

The following HCPCS codes apply for glaucoma screening:

G0117 - Glaucoma screening for high-risk patients furnished by an optometrist or ophthalmologist; and

G0118 - Glaucoma screening for high-risk patients furnished under the direct supervision of an optometrist or ophthalmologist.

The type of service for the above G codes is: TOS Q.

For providers who bill intermediaries, applicable types of bill for screening glaucoma services are 13X, 22X, 23X, 71X, 73X, 75X, and 85X. The following revenue codes should be reported when billing for screening glaucoma services:

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- Comprehensive outpatient rehabilitation facilities (CORFs), critical access hospitals (CAHs), skilled nursing facilities (SNFs), independent and provider-based RHCs and free standing and provider-based FQHCs bill for this service under revenue code 770. CAHs electing the optional method of payment for outpatient services report this service under revenue codes 96X, 97X, or 98X.

- Hospital outpatient departments bill for this service under any valid/appropriate revenue code. They are not required to report revenue code 770.

- **Calculating the Frequency**

- Once a beneficiary has received a covered glaucoma screening procedure, the beneficiary may receive another procedure after 11 full months have passed. To determine the 11-month period, start the count beginning with the month after the month in which the previous covered screening procedure was performed.

- **Diagnosis Coding Requirements**

- Providers bill glaucoma screening using screening (“V”) code V80.1 (Special Screening for Neurological, Eye, and Ear Diseases, Glaucoma). Claims submitted without a screening diagnosis code may be returned to the provider as unprocessable.

- **Payment Methodology**

- **Carriers**

- Contractors pay for glaucoma screening based on the Medicare physician fee schedule. Deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge (refer to the Medicare Claims Processing Manual, Chapter 12, "Physician/Non-physician Practitioners," for more information about the Medicare limiting charge).

- **Intermediaries**

- Payment is made for the facility expense as follows:

- Independent and provider-based RHC/free standing and provider-based FQHC - payment is made under the all inclusive rate for the screening glaucoma service based on the visit furnished to the RHC/FQHC patient;

- CAH - payment is made on a reasonable cost basis unless the CAH has elected the optional method of payment for outpatient services in which case, procedures outlined in the Medicare Claims Processing Manual, Chapter 3, §30.1.1, should be followed;

- CORF - payment is made under the Medicare physician fee schedule;

- Hospital outpatient department - payment is made under outpatient prospective payment system (OPPS);

- Hospital inpatient Part B - payment is made under OPPS;

- SNF outpatient - payment is made under the Medicare physician fee schedule (MPFS); and

- SNF inpatient Part B - payment is made under MPFS.

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Deductible and coinsurance apply.

E. Special Billing Instructions for RHCs and FQHCs

Screening glaucoma services are considered RHC/FQHC services. RHCs and FQHCs bill the contractor under bill type 71X or 73X along with revenue code 770 and HCPCS codes G0117 or G0118 and RHC/FQHC revenue code 520 or 521 to report the related visit. Reporting of revenue code 770 and HCPCS codes G0117 and G0118 in addition to revenue code 520 or 521 is required for this service in order for CWF to perform frequency editing.

Payment should not be made for a screening glaucoma service unless the claim also contains a visit code for the service. Therefore, the contractor installs an edit in its system to assure payment is not made for revenue code 770 unless the claim also contains a visit revenue code (520 or 521).

280.2 - Colorectal Cancer Screening

(Rev. 1, 10-01-03)
B3-4180

280.2.1 - Covered Services and HCPCS Codes

See Business Requirements at http://cms.hhs.gov/manuals/pm_trans/R3BP.pdf
(Rev. 3, 12-19-03)
B3-4180.1

Medicare covers colorectal cancer screening test/procedures for the early detection of colorectal cancer for the HCPCS codes indicated.

A. Effective for Services Furnished On or After January 1, 1998:

G0107 - Colorectal cancer screening; fecal-Occult blood test, 1-3 simultaneous determinations;

G0104 - Colorectal cancer screening; flexible sigmoidoscopy;

G0105 - Colorectal cancer screening; colonoscopy on individual at high risk;

G0106 - Colorectal cancer screening barium enema; alternative to GO104, screening sigmoidoscopy;

G0120 - Colorectal cancer screening barium enema; alternative to GO105, screening sigmoidoscopy.

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B. Effective for Services Furnished On or After July 1, 2001:

G0121 - Colorectal Cancer Screening; Colonoscopy on Individual Not Meeting Criteria for High Risk

C. Effective for Services Furnished On or After January 1, 2004:

G0328 - Colorectal cancer screening; fecal-occult blood test, immunoassay, 1-3 simultaneous determinations.

280.2.2 - Coverage Criteria

(Rev. 3, 12-19-03)
B3-4180.2

The following are the coverage criteria for these screenings:

A. Screening Fecal-Occult Blood Tests (FOBT) (Codes G0107 & G0328)

Effective for services furnished on or after January 1, 2004, one screening FOBT (code G0107 **or** G0328) is covered for beneficiaries who have attained age 50, at a frequency of once every 12 months (i.e., at least 11 months have passed following the month in which the last covered screening FOBT was done). Screening FOBT means: (1) a guaiac-based test for peroxidase activity in which the beneficiary completes it by taking samples from two different sites of three consecutive stools **or**, (2) a immunoassay (or immunochemical) test for antibody activity in which the beneficiary completes the test by taking the appropriate number of samples according to the specific manufacturer's instructions. This expanded coverage is in accordance with revised regulations at 42 CFR 410.37(a)(2) that includes " other tests determined by the Secretary through a national coverage determination." This screening requires a written order from the beneficiary's attending physician. (The term "attending physician" is defined to mean a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act) who is fully knowledgeable about the beneficiary's medical condition, and who would be responsible for using the results of any examination performed in the overall management of the beneficiary's specific medical problem.)

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B. Screening Flexible Sigmoidoscopies (code G0104)

For claims with dates of service on or after January 1, 2002, carriers pay for screening flexible sigmoidoscopies (Code G0104) for beneficiaries who have attained age 50 when these services were performed by a doctor of medicine or osteopathy, or by a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in §1861(aa)(5) of the Act and in the Code of Federal Regulations at 42 CFR 410.74, 410.75, and 410.76) at the frequencies noted below. For claims with dates of service prior to January 1, 2002, pay for these services under the conditions noted only when they are performed by a doctor of medicine or osteopathy.

For services furnished from January 1, 1998, through June 30, 2001, inclusive

Once every 48 months (i.e., at least 47 months have passed following the month in which the last covered screening flexible sigmoidoscopy was done).

For services furnished on or after July 1, 2001

Once every 48 months as calculated above **unless** the beneficiary does not meet the criteria for high risk of developing colorectal cancer (refer to §280.2.3) **and** the beneficiary has had a screening colonoscopy (code G0121) within the preceding 10 years. If such a beneficiary has had a screening colonoscopy within the preceding 10 years, then he or she can have covered a screening flexible sigmoidoscopy only after at least 119

months have passed following the month that he/she received the screening colonoscopy (code G0121).

NOTE: If during the course of a screening flexible sigmoidoscopy a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a flexible sigmoidoscopy with biopsy or removal should be billed and paid rather than code G0104.

C. Screening Colonoscopies for Beneficiaries at High Risk of Developing Colorectal Cancer (Code G0105)

The carrier must pay for screening colonoscopies (code G0105) when performed by a doctor of medicine or osteopathy at a frequency of once every 24 months for beneficiaries at high risk for developing colorectal cancer (i.e., at least 23 months have passed following the month in which the last covered G0105 screening colonoscopy was performed). Refer to §280.2.3 for the criteria to use in determining whether or not an individual is at high risk for developing colorectal cancer.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal should be billed and paid rather than code G0105.

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D. Screening Colonoscopies Performed on Individuals Not Meeting the Criteria for Being at High-Risk for Developing Colorectal Cancer (Code G0121)

Effective for services furnished on or after July 1, 2001, screening colonoscopies (code G0121) are covered when performed under the following conditions:

1. On individuals not meeting the criteria for being at high risk for developing colorectal cancer (refer to §280.2.3);

2. At a frequency of once every 10 years (i.e., at least 119 months have passed following the month in which the last covered G0121 screening colonoscopy was performed); and

3. If the individual would otherwise qualify to have covered a G0121 screening colonoscopy based on the above (see §§280.2.2.D.1 and 2) **but** has had a covered screening flexible sigmoidoscopy (code G0104), then the individual may have a covered G0121 screening colonoscopy only after at least 47 months have passed following the month in which the last covered G0104 flexible sigmoidoscopy was performed.

NOTE: If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure

classified as a colonoscopy with biopsy or removal should be billed and paid rather than code G0121.

E. Screening Barium Enema Examinations (codes G0106 and G0120)

Screening barium enema examinations are covered as an alternative to either a screening sigmoidoscopy (code G0104) or a screening colonoscopy (code G0105) examination. The same frequency parameters for screening sigmoidoscopies and screening colonoscopies above apply.

In the case of an individual aged 50 or over, payment may be made for a screening barium enema examination (code G0106) performed after at least 47 months have passed following the month in which the last screening barium enema or screening flexible sigmoidoscopy was performed. For example, the beneficiary received a screening barium enema examination as an alternative to a screening flexible sigmoidoscopy in January 1999. The count starts beginning February 1999. The beneficiary is eligible for another screening barium enema in January 2003.

In the case of an individual who is at high risk for colorectal cancer, payment may be made for a screening barium enema examination (code G0120) performed after at least 23 months have passed following the month in which the last screening barium enema or the last screening colonoscopy was performed. For example, a beneficiary at high risk for developing colorectal cancer received a screening barium enema examination (code G0120) as an alternative to a screening colonoscopy (code G0105) in January 2000. The count starts beginning February 2000. The beneficiary is eligible for another screening barium enema examination (code G0120) in January 2002.

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The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. Generally, it is expected that this will be a screening double contrast enema unless the individual is unable to withstand such an exam. This means that in the case of a particular individual, the attending physician must determine that the estimated screening potential for the barium enema is equal to or greater than the screening potential that has been estimated for a screening flexible sigmoidoscopy, or for a screening colonoscopy, as appropriate, for the same individual. The screening single contrast barium enema also requires a written order from the beneficiary's attending physician in the same manner as described above for the screening double contrast barium enema examination.

280.2.3 - Determining Whether or Not the Beneficiary is at High Risk for Developing Colorectal Cancer

(Rev. 1, 10-01-03)
B3-4180.3

A. Characteristics of the High Risk Individual

An individual at high risk for developing colorectal cancer has one or more of the following:

A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;

A family history of familial adenomatous polyposis;
A family history of hereditary nonpolyposis colorectal cancer;
A personal history of colorectal cancer;
A personal history of adenomatous polyps;
Inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

B. Partial List of ICD-9-CM Codes Indicating High Risk

Listed below are some examples of diagnoses that meet the high risk criteria for colorectal cancer. This is not an all-inclusive list. There may be more instances of conditions which may be coded and could be at the medical directors' discretion.

- **Personal History**
  - V10.05 - Personal history of malignant neoplasm of large intestine
  - V10.06 - Personal history of malignant neoplasm of rectum, rectosigmoid junction, and anus

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- **Chronic Digestive Disease Condition**
  - 555.0 - Regional enteritis of small intestine
  - 555.1 - Regional enteritis of large intestine
  - 555.2 - Regional enteritis of small intestine with large intestine
  - 555.9 - Regional enteritis of unspecified site
  - 556.0 - Ulcerative (chronic) enterocolitis
  - 556.1 - Ulcerative (chronic) ileocolitis
  - 556.2 - Ulcerative (chronic) proctitis
  - 556.3 - Ulcerative (chronic) proctosigmoiditis
  - 556.8 - Other ulcerative colitis
  - 556.9 - Ulcerative colitis, unspecified (nonspecific PDX on the MCE)

- **Inflammatory Bowel**
  - 558.2 - Toxic gastroenteritis and colitis
  - 558.9 - Other and unspecified noninfectious gastroenteritis and colitis

280.2.4 - Determining Frequency Standards
(Rev. 1, 10-01-03)
B3-4180.4

To determine the 11, 23, 47, and 119-month periods, the count starts beginning with the month after the month in which a previous test/procedure was performed.

EXAMPLE: The beneficiary received a fecal-occult blood test in January 2000. The carrier starts its count beginning with February 2000. The beneficiary is eligible to receive another blood test in January 2001 (the month after 11 full months have passed).

280.2.5 - Noncovered Services
(Rev. 1, 10-01-03)
B3-4180.5

The following noncovered HCPCS codes are used to allow claims to be billed and denied for beneficiaries who need a Medicare denial for other insurance purposes for the dates of service indicated:

A. From January 1, 1998 Through June 30, 2001, Inclusive

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Code G0121 (colorectal cancer screening; colonoscopy on an individual not meeting criteria for high risk) should be used when this procedure is performed on a beneficiary who does NOT meet the criteria for high risk. This service should be denied as noncovered because it fails to meet the requirements of the benefit for these dates of service. The beneficiary is liable for payment. Note that this code is a covered service for dates of service on or after July 1, 2001.

B. On or After January 1, 1998

Code G0122 (colorectal cancer screening; barium enema) should be used when a screening barium enema is performed NOT as an alternative to either a screening colonoscopy (code G0105) or a screening flexible sigmoidoscopy (code G0104). This service should be denied as noncovered because it fails to meet the requirements of the benefit. The beneficiary is liable for payment.

280.3 - Screening Mammography
(Rev. 1, 10-01-03)
A3-3660.10, B3-4601.1

Section 4163 of the Omnibus Budget Reconciliation Act of 1990 added §1834(c) of the Act to provide for Part B coverage of mammography screening performed on or after January 1, 1991. The term “screening mammography” means a radiologic procedure provided to an asymptomatic woman for the purpose of early detection of breast cancer and includes a physician’s interpretation of the results of the procedure. Unlike

diagnostic mammographies, there do not need to be signs, symptoms, or history of breast disease in order for the exam to be covered.

A doctor's prescription or referral is not necessary for the procedure to be covered. Payment may be made for a screening mammography furnished to a woman at her direct request, and based on a woman's age and statutory frequency parameter.

Section 4101 of the Balanced Budget Act (BBA) of 1997 provides for annual screening mammographies for women over 39 and waives the Part B deductible. Coverage applies as follows:

Age	**Screening Period**
Less than 35 years old	No payment may be made for a screening mammography performed on a woman under 35 years of age.
35-39	(Baseline). Pay for only one screening mammography performed on a woman between her 35th and 40th birthday.
Over age 39	For a woman over 39, pay for a screening mammography performed after 11 full months have passed following the month in which the last screening mammography was performed.

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To determine the 11-month period, intermediaries and carriers start counting beginning with the month after the month in which a previous screening mammography was performed.

EXAMPLE: If Mrs. Smith received a screening mammography examination in January 1998, begin counting the next month (February 1998) until 11 months have elapsed. Payment can be made for another screening mammography in January 1999.

See the Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," §30, for billing and payment instructions.

280.4 - Screening Pap Smears

(Rev. 1, 10-01-03)
A3-3628.1, B3-4603.1

Effective, January 1, 1998, §4102 of the Balanced Budget Act (BBA) of 1997 (P.L. 105-33) amended §1861(nn) of the Act (42 USC 1395X(nn)) to include coverage every three years for a screening Pap smear or more frequent coverage for women:

1. At high risk for cervical or vaginal cancer; or

2. Of childbearing age who have had a Pap smear during any of the preceding three years indicating the presence of cervical or vaginal cancer or other abnormality.

Effective July 1, 2001, the Consolidated Appropriations Act of 2001 (P.L. 106-554) modifies §1861(nn) to provide Medicare coverage for biennial screening Pap smears. Specifications for frequency limitations are defined below.

For claims with dates of service from January 1, 1998, through June 30, 2001, screening Pap smears are covered when ordered and collected by a doctor of medicine or osteopathy (as defined in §1861(r)(1) of the Act), or other authorized practitioner (e.g., a certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist, who is authorized under State law to perform the examination) under one of the following conditions.

The beneficiary has not had a screening Pap smear test during the preceding three years (i.e., 35 months have passed following the month that the woman had the last covered Pap smear ICD-9-CM code V76.2 is used to indicate special screening for malignant neoplasm, cervix); or

There is evidence (on the basis of her medical history or other findings) that she is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or other abnormalities during any of the preceding three years; and at least 11 months have passed following the month that the last covered Pap smear was performed; or

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She is at high risk of developing cervical or vaginal cancer ICD-9-CM code V15.89, other specified personal history presenting hazards to health) and at least 11 months have passed following the month that the last covered screening Pap smear was performed. The high risk factors for cervical and vaginal cancer are:

Cervical Cancer High Risk Factors

Early onset of sexual activity (under 16 years of age);

Multiple sexual partners (five or more in a lifetime);

History of a sexually transmitted disease (including HIV infection); and

Fewer than three negative or any Pap smears within the previous seven years.

Vaginal Cancer High Risk Factors

The DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy

The term “woman of childbearing age” means a woman who is premenopausal, and has been determined by a physician, or qualified practitioner, to be of childbearing age, based on her medical history or other findings. Payment is not made for a screening Pap smear

for women at high risk or who qualify for coverage under the childbearing provision more frequently than once every 11 months after the month that the last screening Pap smear covered by Medicare was performed.

B. For Claims with Dates of Service on or After July 1, 2001

When the beneficiary does not qualify for a more frequently performed screening Pap smear as noted in items 1 and 2 above, contractors pay for the screening Pap smear only after at least 23 months have passed following the month during which the beneficiary received her last covered screening Pap smear. All other coverage and payment requirements remain the same.

See the Medicare Claims Processing Manual, Chapter 18, "Preventive and Screening Services," for billing procedures.

280.5 – Annual Wellness Visit (AWV) Including Personalized Prevention Plan Services (PPPS)

(Rev. 138, Issued: 02-15-11, Effective: 01-01-11, Implementation: 04-04-11)

A. General

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Pursuant to section 4103 of the Affordable Care Act of 2010 (the ACA), the Centers for Medicare & Medicaid Services (CMS) amended section 411.15(a)(1) and 411.15(k)(15) of the Code of Federal Regulations (CFR)(list of examples of routine physical examinations excluded from coverage), effective for services furnished on or after January 1, 2011. This expanded coverage, as established at 42 CFR 410.15, is subject to certain eligibility and other limitations that allow payment for an annual wellness visit (AWV), including personalized prevention plan services (PPPS), when performed by qualified health professionals, for an individual who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period, and has not received either an initial preventive physical examination (IPPE) or an AWV within the past 12 months. Medicare coinsurance and Part B deductibles do not apply.

The AWV will include the establishment of, or update to, the individual's medical/family history, measurement of his/her height, weight, body-mass index (BMI) or waist circumference, and blood pressure (BP), with the goal of health promotion and disease detection and encouraging patients to obtain the screening and preventive services that may already be covered and paid for under Medicare Part B. Definitions relative to the AWV are included below.

Coverage is available for an AWV that meets the following requirements:

1. It is performed by a health professional; and,

2. It is furnished to an eligible beneficiary who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period, and he/she has not received either an IPPE or an AWV providing PPPS within the past 12 months.

Sections 4103 and 4104 of the ACA also provide for a waiver of the Medicare coinsurance and Part B deductible requirements for an AWV effective for services furnished on or after January 1, 2011.

B. Definitions Relative to the AWV:

Detection of any cognitive impairment: The assessment of an individual's cognitive function by direct observation, with due consideration of information obtained by way of patient reports, concerns raised by family members, friends, caretakers, or others.

Eligible beneficiary: An individual who is no longer within 12 months after the effective date of his/her first Medicare Part B coverage period and who has not received either an IPPE or an AWV providing PPPS within the past 12 months.

Establishment of, or an update to, the individual's medical/family history: At a minimum, the collection and documentation of the following:

a. Past medical and surgical history, including experiences with illnesses, hospital stays, operations, allergies, injuries, and treatments.

b. Use or exposure to medications and supplements, including calcium and vitamins.

c. Medical events in the beneficiary's parents and any siblings and children, including diseases that may be hereditary or place the individual at increased risk.

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First AWV providing PPPS: The provision of the following services to an eligible beneficiary by a health professional as those terms are defined in this section:

a. Establishment of an individual's medical/family history.

b. Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.

c. Measurement of an individual's height, weight, BMI (or waist circumference, if appropriate), BP, and other routine measurements as deemed appropriate, based on the beneficiary's medical/family history.

d. Detection of any cognitive impairment that the individual may have as defined in this section.

e. Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an

appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.

f. Review of the individual's functional ability and level of safety based on direct observation, or the use of appropriate screening questions or a screening questionnaire, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.

g. Establishment of the following:

(1) A written screening schedule for the individual, such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP), as well as the individual's health status, screening history, and age-appropriate preventive services covered by Medicare.

(2) A list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE, and a list of treatment options and their associated risks and benefits.

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h. Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

i. Any other element determined appropriate through the National Coverage Determination (NCD) process.

<u>Health professional:</u>

a. A physician who is a doctor of medicine or osteopathy (as defined in section 1861(r)(1) of the Social Security Act (the Act); or,

b. A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1861(aa)(5) of the Act); or,

c. A medical professional (including a health educator, registered dietitian, or nutrition professional or other licensed practitioner) or a team of such medical professionals, working under the direct supervision (as defined in 42CFR 410.32(b)(3)(ii)) of a physician as defined in this section.

Review of the individual's functional ability and level of safety: At a minimum, includes assessment of the following topics:

a. Hearing impairment,

b. Ability to successfully perform activities of daily living,

c. Fall risk, and,

d. Home safety.

Subsequent AWV providing PPPS: The provision of the following services to an eligible beneficiary by a health professional as those terms are defined in this section:

a. An update of the individual's medical/family history.

b. An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual, as that list was developed for the first AWV providing PPPS.

c. Measurement of an individual's weight (or waist circumference), BP, and other routine measurements as deemed appropriate, based on the individual's medical/family history.

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d. Detection of any cognitive impairment that the individual may have as defined in this section.

e. An update to the following:

(1) The written screening schedule for the individual as that schedule is defined in this section, that was developed at the first AWV providing PPPS, and,

(2) The list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are under way for the individual, as that list was developed at the first AWV providing PPPS.

f. Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined for the first AWV providing PPPS.

g. Any other element determined appropriate by the Secretary through the NCD process.

See Pub. 100-04, Medicare Claims Processing Manual, chapter 18, section 140, for detailed claims processing and billing instructions.

290 - Foot Care
(Rev. 1, 10-01-03)
A3-3158, B3-2323, HO-260.9, B3-4120.1

A. Treatment of Subluxation of Foot

Subluxations of the foot are defined as partial dislocations or displacements of joint surfaces, tendons ligaments, or muscles of the foot. Surgical or nonsurgical treatments undertaken for the sole purpose of correcting a subluxated structure in the foot as an isolated entity are not covered.

However, medical or surgical treatment of subluxation of the ankle joint (talo-crural joint) is covered. In addition, reasonable and necessary medical or surgical services, diagnosis, or treatment for medical conditions that have resulted from or are associated with partial displacement of structures is covered. For example, if a patient has osteoarthritis that has resulted in a partial displacement of joints in the foot, and the primary treatment is for the osteoarthritis, coverage is provided.

B. Exclusions from Coverage

The following foot care services are generally excluded from coverage under both Part A and Part B. (See §290.F and §290.G for instructions on applying foot care exclusions.)

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1. Treatment of Flat Foot

The term "flat foot" is defined as a condition in which one or more arches of the foot have flattened out. Services or devices directed toward the care or correction of such conditions, including the prescription of supportive devices, are not covered.

2. Routine Foot Care

Except as provided above, routine foot care is excluded from coverage. Services that normally are considered routine and not covered by Medicare include the following:

- The cutting or removal of corns and calluses;
- The trimming, cutting, clipping, or debriding of nails; and
- Other hygienic and preventive maintenance care, such as cleaning and soaking the feet, the use of skin creams to maintain skin tone of either ambulatory or bedfast patients, and any other service performed in the absence of localized illness, injury, or symptoms involving the foot.

3. Supportive Devices for Feet

Orthopedic shoes and other supportive devices for the feet generally are not covered. However, this exclusion does not apply to such a shoe if it is an integral part of a leg brace, and its expense is included as part of the cost of the brace. Also, this exclusion does not apply to therapeutic shoes furnished to diabetics.

C. Exceptions to Routine Foot Care Exclusion

1. Necessary and Integral Part of Otherwise Covered Services

In certain circumstances, services ordinarily considered to be routine may be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of ulcers, wounds, or infections.

2. Treatment of Warts on Foot

The treatment of warts (including plantar warts) on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body.

3. Presence of Systemic Condition

The presence of a systemic condition such as metabolic, neurologic, or peripheral vascular disease may require scrupulous foot care by a professional that in the absence of such condition(s) would be considered routine (and, therefore, excluded from coverage). Accordingly, foot care that would otherwise be considered routine may be covered when systemic condition(s) result in severe circulatory embarrassment or areas of diminished sensation in the individual's legs or feet. (See subsection A.)

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In these instances, certain foot care procedures that otherwise are considered routine (e.g., cutting or removing corns and calluses, or trimming, cutting, clipping, or debriding nails) may pose a hazard when performed by a nonprofessional person on patients with such systemic conditions. (See §290.G for procedural instructions.)

4. Mycotic Nails

In the absence of a systemic condition, treatment of mycotic nails may be covered.

The treatment of mycotic nails for an ambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient has marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

The treatment of mycotic nails for a nonambulatory patient is covered only when the physician attending the patient's mycotic condition documents that (1) there is clinical evidence of mycosis of the toenail, and (2) the patient suffers from pain or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

For the purpose of these requirements, documentation means any written information that is required by the carrier in order for services to be covered. Thus, the information submitted with claims must be substantiated by information found in the patient's medical record. Any information, including that contained in a form letter, used for documentation purposes is subject to carrier verification in order to ensure that the information adequately justifies coverage of the treatment of mycotic nails.

D. Systemic Conditions That Might Justify Coverage

Although not intended as a comprehensive list, the following metabolic, neurologic, and peripheral vascular diseases (with synonyms in parentheses) most commonly represent the underlying conditions that might justify coverage for routine foot care.

Diabetes mellitus *

Arteriosclerosis obliterans (A.S.O., arteriosclerosis of the extremities, occlusive peripheral arteriosclerosis)

Buerger's disease (thromboangiitis obliterans)

Chronic thrombophlebitis *

Peripheral neuropathies involving the feet -

Associated with malnutrition and vitamin deficiency *

- Malnutrition (general, pellagra)
- Alcoholism
- Malabsorption (celiac disease, tropical sprue)
- Pernicious anemia

Associated with carcinoma *

Associated with diabetes mellitus *

Associated with drugs and toxins *

Associated with multiple sclerosis *

Associated with uremia (chronic renal disease) *

Associated with traumatic injury

Associated with leprosy or neurosyphilis

Associated with hereditary disorders

- Hereditary sensory radicular neuropathy
- Angiokeratoma corporis diffusum (Fabry's)
- Amyloid neuropathy

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When the patient's condition is one of those designated by an asterisk (*), routine procedures are covered only if the patient is under the active care of a doctor of medicine or osteopathy who documents the condition.

E. Supportive Devices for Feet

Orthopedic shoes and other supportive devices for the feet generally are not covered. However, this exclusion does not apply to such a shoe if it is an integral part of a leg brace, and its expense is included as part of the cost of the brace. Also, this exclusion does not apply to therapeutic shoes furnished to diabetics.

F. Presumption of Coverage

In evaluating whether the routine services can be reimbursed, a presumption of coverage may be made where the evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption the following findings are pertinent:

Class A Findings

Nontraumatic amputation of foot or integral skeletal portion thereof.

Class B Findings

Absent posterior tibial pulse;

Advanced trophic changes as: hair growth (decrease or absence) nail changes (thickening) pigmentary changes (discoloration) skin texture (thin, shiny) skin color (rubor or redness) (Three required); and

Absent dorsalis pedis pulse.

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Class C Findings

Claudication;

Temperature changes (e.g., cold feet);

Edema;

Paresthesias (abnormal spontaneous sensations in the feet); and

Burning.

The presumption of coverage may be applied when the physician rendering the routine foot care has identified:

1. A Class A finding;
2. Two of the Class B findings; or
3. One Class B and two Class C findings.

Cases evidencing findings falling short of these alternatives may involve podiatric treatment that may constitute covered care and should be reviewed by the intermediary's medical staff and developed as necessary.

For purposes of applying the coverage presumption where the routine services have been rendered by a podiatrist, the contractor may deem the active care requirement met if the claim or other evidence available discloses that the patient has seen an M.D. or D.O. for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type services. The intermediary may also accept the podiatrist's statement that the diagnosing and treating M.D. or D.O. also concurs with the podiatrist's findings as to the severity of the peripheral involvement indicated.

Services ordinarily considered routine might also be covered if they are performed as a necessary and integral part of otherwise covered services, such as diagnosis and treatment of diabetic ulcers, wounds, and infections.

G. Application of Foot Care Exclusions to Physician's Services

The exclusion of foot care is determined by the nature of the service. Thus, payment for an excluded service should be denied whether performed by a podiatrist, osteopath, or a doctor of medicine, and without regard to the difficulty or complexity of the procedure.

When an itemized bill shows both covered services and noncovered services not integrally related to the covered service, the portion of charges attributable to the noncovered services should be denied. (For example, if an itemized bill shows surgery for an ingrown toenail and also removal of calluses not necessary for the performance of toe surgery, any additional charge attributable to removal of the calluses should be denied.)

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In reviewing claims involving foot care, the carrier should be alert to the following exceptional situations:

1. Payment may be made for incidental noncovered services performed as a necessary and integral part of, and secondary to, a covered procedure. For example, if trimming of toenails is required for application of a cast to a fractured foot, the carrier need not allocate and deny a portion of the charge for the trimming of the nails. However, a separately itemized charge for such excluded service should be disallowed. When the primary procedure is covered the administration of anesthesia necessary for the performance of such procedure is also covered.

2. Payment may be made for **initial** diagnostic services performed in connection with a specific symptom or complaint if it seems likely that its treatment would be covered even though the resulting diagnosis may be one requiring only noncovered care.

The name of the M.D. or D.O. who diagnosed the complicating condition must be submitted with the claim. In those cases, where active care is required, the approximate date the beneficiary was last seen by such physician must also be indicated.

NOTE: Section 939 of P.L. 96-499 removed "warts" from the routine foot care exclusion effective July 1, 1981.

Relatively few claims for routine-type care are anticipated considering the severity of conditions contemplated as the basis for this exception. Claims for this type of foot care should not be paid in the absence of convincing evidence that nonprofessional performance of the service would have been hazardous for the beneficiary because of an underlying systemic disease. The mere statement of a diagnosis such as those mentioned in §D above does not of itself indicate the severity of the condition. Where development is indicated to verify diagnosis and/or severity the carrier should follow existing claims processing practices, which may include review of carrier's history and medical consultation as well as physician contacts.

The rules in §290.F concerning presumption of coverage also apply.

Codes and policies for routine foot care and supportive devices for the feet are not exclusively for the use of podiatrists. These codes must be used to report foot care services regardless of the specialty of the physician who furnishes the services. Carriers must instruct physicians to use the most appropriate code available when billing for routine foot care.

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300 - Diabetes Self-Management Training Services

(Rev. 72, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Section 4105 of the Balanced Budget Act of 1997 permits Medicare coverage of diabetes self-management training (DSMT) services when these services are furnished by a certified provider who meets certain quality standards. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin-dependent; and motivation for patients to use the skills for self-management.

Diabetes self-management training services may be covered by Medicare only if the treating physician or treating qualified non-physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed. The referring physician or qualified non-physician practitioner must maintain the plan of care in the beneficiary's medical record and documentation substantiating the need for training on an individual basis when group training is typically covered, if so ordered. The order must also include a statement signed by the physician that the service is needed as well as the following:

- The number of initial or follow-up hours ordered (the physician can order less than 10 hours of training);

- The topics to be covered in training (initial training hours can be used for the full initial training program or specific areas such as nutrition or insulin training); and

- A determination that the beneficiary should receive individual or group training.

The provider of the service must maintain documentation in a file that includes the original order from the physician and any special conditions noted by the physician.

When the training under the order is changed, the training order/referral must be signed by the physician or qualified non-physician practitioner treating the beneficiary and maintained in the beneficiary's file in the DSMT's program records.

NOTE: All entities billing for DSMT under the fee-for-service payment system or other payment systems must meet all national coverage requirements.

300.1 - Beneficiaries Eligible for Coverage and Definition of Diabetes
(Rev. 13, 05-13-04)

Medicare Part B covers 10 hours of initial training for a beneficiary who has been diagnosed with diabetes.

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Diabetes is diabetes mellitus, a condition of abnormal glucose metabolism diagnosed using the following criteria:

- a fasting blood sugar greater than or equal to 126 mg/dL on two different occasions;

- a 2 hour post-glucose challenge greater than or equal to 200 mg/dL on 2 different occasions; or

- a random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.

Documentation that the beneficiary is diabetic is maintained in the beneficiary's medical record.

Beneficiaries are eligible to receive follow-up training each calendar year following the year in which they have been certified as requiring initial training or they may receive follow-up training when ordered even if Medicare does not have documentation that initial training has been received. In that instance, contractors shall not deny the follow-up service even though there is no initial training recorded.

300.2 - Certified Providers

(Rev. 109; Issued: 08-07-09; Effective Date: 03-30-09; Implementation Date: 09-08-09)

A designated certified provider bills for DSMT provided by an accredited DSMT program. Certified providers must submit a copy of their accreditation certificate to the contractor. The statute states that a "certified provider" is a physician or other individual or entity designated by the Secretary that, in addition to providing outpatient self-management training services, provides other items and services for which payment may be made under title XVIII, and meets certain quality standards. The CMS is designating all providers and suppliers that bill Medicare for other individual services such as hospital outpatient departments, renal dialysis facilities, physicians and durable medical equipment suppliers as certified. All suppliers/providers who may bill for other Medicare services or items and who represent a DSMT program that is accredited as meeting quality standards can bill and receive payment for the entire DSMT program. Registered dietitians are eligible to bill on behalf of an entire DSMT program on or after January 1, 2002, as long as the provider has obtained a Medicare provider number. A dietitian may not be the sole provider of the DSMT service. There is an exception for rural areas. In a rural area, an individual who is qualified as a registered dietitian and as a certified diabetic educator who is currently certified by an organization approved by CMS may furnish training and is deemed to meet the multidisciplinary team requirement.

The CMS will not reimburse services on a fee-for-service basis rendered to a beneficiary under Part A.

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NOTE: While separate payment is not made for this service to Rural Health Clinics (RHCs), the service is covered but is considered included in the all-inclusive encounter rate. Effective January 1, 2006, payment for DSMT provided in a Federally Qualified Health Clinic (FQHC) that meets all of the requirements identified in Pub. 100-04, chapter 18, section 120 may be made in addition to one other visit the beneficiary had during the same day.

All DSMT programs must be accredited as meeting quality standards by a CMS approved national accreditation organization. Currently, CMS recognizes the American Diabetes Association, American Association of Diabetes Educators and the Indian Health Service as approved national accreditation organizations. Programs without accreditation by a CMS-approved national accreditation organization are not covered. Certified providers may be asked to submit updated accreditation documents at any time or to submit outcome data to an organization designated by CMS.

Enrollment of DMEPOS Suppliers

The DMEPOS suppliers are reimbursed for diabetes training through local carriers. In order to file claims for DSMT, a DMEPOS supplier must be enrolled in the Medicare program with the National Supplier Clearinghouse (NSC). The supplier must also meet the quality standards of a CMS-approved national accreditation organization as stated

above. DMEPOS suppliers must obtain a provider number from the local carrier in order to bill for DSMT.

The carrier requires a completed Form CMS-855, along with an accreditation certificate as part of the provider application process. After it has been determined that the quality standards are met, a billing number is assigned to the supplier. Once a supplier has received a National Provider Identification (NPI) number, the supplier can begin receiving reimbursement for this service.

Carriers should contact the National Supplier Clearinghouse (NSC) according to the instruction in Pub 100-08, the Medicare Program Integrity Manual, Chapter 10, "Healthcare Provider/Supplier Enrollment," to verify an applicant is currently enrolled and eligible to receive direct payment from the Medicare program.

The applicant is assigned specialty 87.

Any DMEPOS supplier that has its billing privileges deactivated or revoked by the NSC will also have the billing number deactivated by the carrier.

300.3 - Frequency of Training

(Rev. 72, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

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A - Initial Training

The initial year for DSMT is the 12 month period following the initial date.

Medicare will cover initial training that meets the following conditions:

- Is furnished to a beneficiary who has not previously received initial or follow-up training under HCPCS codes G0108 or G0109;
- Is furnished within a continuous 12-month period;
- Does not exceed a total of 10 hours* (the 10 hours of training can be done in any combination of 1/2 hour increments);
- With the exception of 1 hour of individual training, training is usually furnished in a group setting, which can contain other patients besides Medicare beneficiaries, and;
- One hour of individual training may be used for any part of the training including insulin training.

* When a claim contains a DSMT HCPCS code and the associated units cause the total time for the DSMT initial year to exceed '10' hours, a CWF error will set.

B - Follow-Up Training

Medicare covers follow-up training under the following conditions:

- No more than 2 hours individual or group training per beneficiary per year;
- Group training consists of 2 to 20 individuals who need not all be Medicare beneficiaries;
- Follow-up training for subsequent years is based on a 12 month calendar after completion of the full 10 hours of initial training;
- Follow-up training is furnished in increments of no less than one-half hour*; and
- The physician (or qualified non-physician practitioner) treating the beneficiary must document in the beneficiary's medical record that the beneficiary is a diabetic.

  *When a claim contains a DSMT HCPCS code and the associated units cause the total time for any follow-up year to exceed 2 hours, a CWF error will set.

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300.4 - Coverage Requirements for Individual Training

(Rev. 72, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Medicare covers training on an individual basis for a Medicare beneficiary under any of the following conditions:

- No group session is available within 2 months of the date the training is ordered;
- The beneficiary's physician (or qualified non-physician practitioner) documents in the beneficiary's medical record that the beneficiary has special needs resulting from conditions, such as severe vision, hearing or language limitations or other such special conditions as identified by the treating physician or non-physician practitioner, that will hinder effective participation in a group training session; or
- The physician orders additional insulin training.
- The need for individual training must be identified by the physician or non-physician practitioner in the referral.

  NOTE: If individual training has been provided to a Medicare beneficiary and subsequently the carrier or intermediary determines that training should have been provided in a group, carriers and intermediaries down-code the reimbursement from individual to the group level and provider education would be the appropriate actions instead of denying the service as billed.

300.4.1 – Incident-To Provision
(Rev. 13, 05-13-04)

The "incident to" requirements of section 1861(s)(2)(A) of the Social Security Act do not apply to DSMT services. Section 1861 (s)(2)(S) of the Act authorizes DSMT in a stand alone provision. DSMT services are covered only if the physician or qualified non-physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed and refers the patient to the DSMT program. The referral must be done under a comprehensive plan of care related to the beneficiary's diabetic condition. Training may be furnished by a physician, individual, or entity that meets the following conditions:

- Furnishes other services for which direct Medicare payment may be made;
- May properly receive Medicare payment under 42CFR 424.73 or 424.80 which set forth prohibitions on assignment and reassignment of claims;
- Submits necessary documentation to, and is accredited by, an accreditation organization approved by CMS under 42CFR 410.142 to meet one of the sets of quality standards described in 42 CFR 410.144; and

Provides documentation to CMS, as requested, including diabetes outcome measurements set forth at CFR 410.146

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Any certified providers or suppliers that provide other individual items or services under Medicare that meet CMS's quality standards and meet the conditions for CMS approval pursuant to 42 CFR 410.145, may receive reimbursement for diabetes training. Entities are more likely than individuals to bill for DSMT services. These certified providers must be currently receiving payment for other Medicare services.

300.5 - Payment for DSMT
(Rev. 72, Issued: 05-25-07; Effective: 07-01-07; Implementation: 07-02-07)

Payment for DSMT may only be made to any provider that bills Medicare for other individual Medicare services and may be made only for training sessions actually attended by the beneficiary and documented on attendance sheets.

See Pub. 100-04, chapter 18, section 120 for specific payment information for physicians and all provider types.

300.5.1 - Special Claims Processing Instructions for FIs
(Rev. 24, Issued: 10-29-04, Effective: 01-01-05, Implementation: 01-03-05)

- Coding and Payment Requirements

The provider bills for DSMT on Form CMS-1450 or its electronic equivalent. The cost of the service is billed under revenue code 942 in FL 42 "Revenue Code." The provider will report HCPCS codes G0108 or G0109 in FL 44 "HCPCS/Rates." The definition of the HCPCS code used should be entered in FL 43 "Description."

- Applicable Bill Types

  The appropriate bill types are 12x, 22x, 13x, 34x (can be billed if service is outside of the treatment plan), 72x, 74x, 75x, 83x and 85x.

310 – Kidney Disease Patient Education Services

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

By definition, chronic kidney disease (CKD) is kidney damage for 3 months or longer, regardless of the cause of kidney damage. CKD typically evolves over a long period of time and patients may not have symptoms until significant, possibly irreversible, damage has been done. Complications can develop from kidneys that do not function properly, such as high blood pressure, anemia, and weak bones. When CKD progresses, it may lead to kidney failure, which requires artificial means to perform kidney functions (dialysis) or a kidney transplant to maintain life.

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Patients can be classified into 5 stages based on their glomerular filtration rate (GFR, how quickly blood is filtered through the kidneys), with stage I having kidney damage with normal or increased GFR to stage V with kidney failure, also called end-stage renal disease (ESRD). Once patients with CKD are identified, treatment is available to help prevent complications of decreased kidney function, slow the progression of kidney disease, and reduce the risk of other diseases such as heart disease.

Beneficiaries with CKD may benefit from kidney disease education (KDE) interventions due to the large amount of medical information that could affect patient outcomes, including the increasing emphasis on self-care and patients' desire for informed, autonomous decision-making. Pre-dialysis education can help patients achieve better understanding of their illness, dialysis modality options, and may help delay the need for dialysis. Education interventions should be patient-centered, encourage collaboration, offer support to the patient, and be delivered consistently.

Effective for claims with dates of service on and after January 1, 2010, Section 152(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) covers KDE services under Medicare Part B. KDE services are designed to provide beneficiaries with Stage IV CKD comprehensive information regarding: the management of comorbidities, including delaying the need for dialysis; prevention of uremic complications; all therapeutic options (each option for renal replacement therapy, dialysis

access options, and transplantation); ensuring that the beneficiary has opportunities to actively participate in his/her choice of therapy; and that the services be tailored to meet the beneficiary's needs.

Regulations for KDE services were established at 42 CFR 410.48. Claims processing instructions and billing requirements can be found in Pub. 100-04, Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, Section 20.

310.1 - Beneficiaries Eligible for Coverage

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers outpatient, face-to-face KDE services for a beneficiary that:

- is diagnosed with Stage IV CKD, using the Modification of Diet in Renal Disease (MDRD) Study formula (severe decrease in GFR, GFR value of 15-29 mL/min/1.73 m^2), and

- obtains a referral from the physician managing the beneficiary's kidney condition. The referral should be documented in the beneficiary's medical records.

310.2 - Qualified Person

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

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Medicare Part B covers KDE services provided by a 'qualified person,' meaning a:

- physician (as defined in section 30 of this chapter),

- physician assistant, nurse practitioner, or clinical nurse specialist (as defined in sections 190, 200, and 210 of this chapter),

- hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), or hospice, if the KDE services are provided in a rural area (using the actual geographic location core based statistical area (CBSA) to identify facilities located in rural areas), or

- hospital or CAH that is treated as being rural (was reclassified from urban to rural status per 42 CFR 412.103).

NOTE: The "incident to" requirements at section 1861(s)(2)(A) of the Social Security Act (the Act) do not apply to KDE services.

The following providers are not 'qualified persons' and are excluded from furnishing KDE services:

- A hospital, CAH, SNF, CORF, HHA, or hospice located outside of a rural area (using the actual geographic location CBSA to identify facilities located outside of a rural area), unless the services are furnished by a hospital or CAH that is treated as being in a rural area; and

- Renal dialysis facilities.

310.3 - Limitations for Coverage

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers KDE services:

- Up to six (6) sessions as a beneficiary lifetime maximum. A session is 1 hour. In order to bill for a session, a session must be at least 31 minutes in duration. A session that lasts at least 31 minutes, but less than 1 hour still constitutes 1 session.

- On an individual basis or in group settings; if the services are provided in a group setting, a group consists of 2 to 20 individuals who need not all be Medicare beneficiaries**.**

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NOTE: Two HCPCS codes were created for this benefit and one or the other must be present, along with ICD-9-CM code 585.4 (chronic kidney disease, Stage IV (severe)), in order for a claim to be processed and paid correctly. They are:

- G0420: Face-to-face educational services related to the care of chronic kidney disease; individual, per session, per one hour

- G0421: Face-to-face educational services related to the care of chronic kidney disease; group, per session, per one hour

310.4 – Standards for Content

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Medicare Part B covers KDE services, provided by a qualified person, which provide comprehensive information regarding:

A. The management of comorbidities, including delaying the need for dialysis, which includes, but is not limited to, the following topics:

- Prevention and treatment of cardiovascular disease,
- Prevention and treatment of diabetes,

- Hypertension management,
- Anemia management,
- Bone disease and disorders of calcium and phosphorus metabolism management,
- Symptomatic neuropathy management, and
- Impairments in functioning and well-being.

B. Prevention of uremic complications, which includes, but is not limited to, the following topics:

- Information on how the kidneys work and what happens when the kidneys fail,
- Understanding if remaining kidney function can be protected, preventing disease progression, and realistic chances of survival,
- Diet and fluid restrictions, and
- Medication review, including how each medication works, possible side effects and minimization of side effects, the importance of compliance, and informed decision making if the patient decides not to take a specific drug.

C. Therapeutic options, treatment modalities and settings, advantages and disadvantages of each treatment option, and how the treatments replace the kidney, including, but not limited to, the following topics:

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- Hemodialysis, both at home and in-facility;
- Peritoneal dialysis (PD), including intermittent PD, continuous ambulatory PD, and continuous cycling PD, both at home and in-facility;
- All dialysis access options for hemodialysis and peritoneal dialysis; and
- Transplantation.

D. Opportunities for beneficiaries to actively participate in the choice of therapy and be tailored to meet the needs of the individual beneficiary involved, which includes, but is not limited to, the following topics:

- Physical symptoms,
- Impact on family and social life,
- Exercise,
- The right to refuse treatment,
- Impact on work and finances,
- The meaning of test results, and
- Psychological impact.

310.5 - Outcomes Assessment

(Rev. 117; Issued: 12-18-09; Effective Date: 01-01-10; Implementation Date: 04-05-10)

Qualified persons that provide KDE services must develop outcomes assessments that are designed to measure beneficiary knowledge about CKD and its treatment. The assessment must be administered to the beneficiary during a KDE session, and be made available to the Centers for Medicare & Medicaid Services (CMS) upon request. The outcomes assessments serve to assist KDE educators and CMS in improving subsequent KDE programs, patient understanding, and assess program effectiveness of:

- Preparing the beneficiary to make informed decisions about their healthcare options related to CKD, and

- Meeting the communication needs of underserved populations, including persons with disabilities, persons with limited English proficiency, and persons with health literacy needs**.**

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Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R157BP	06-08-2012	July 2012 Update of the Hospital Outpatient Prospective Payment System (OPPS)	07/02/2012	7847
R151BP	11/18/2011	Expansion of Medicare Telehealth Services for CY 2012	01/03/2012	7504
R147BP	08/26/2011	Clarification of Evaluation and Management Payment Policy	11/28/2011	7405
R146BP	08/12/2011	Expansion of Medicare Telehealth Services for CY 2012 – Rescinded and replaced by Transmittal 151	01/03/2012	7504
R145BP	07/08/2011	Influenza Virus Vaccine	08/08/2011	7453
R140BP	02/28/2011	Expansion of Medicare Telehealth Services for CY 2011	01/03/2011 & 04/04/2011	7049
R138BP	02/15/2011	Annual Wellness Visit (AWV), Including Personalized Prevention Plan Services (PPPS)	04/04/2011	7079
R134BP	12/03/2010	Annual Wellness Visit (AWV), Including Personalized Prevention Plan Services (PPPS) – Rescinded and replaced by Transmittal 138	04/04/2011	7079
R132BP	09/03/2010	Revisions and Re-issuance of Audiology Policies	09/30/2010	6447
R131BP	08/20/2010	Expansion of Medicare Telehealth Services for CY 2011 – Rescinded and replaced by Transmittal 140	01/03/2011	7049
R129BP	07/23/2010	Revisions and Re-issuance of Audiology Policies - Rescinded and replaced by Transmittal 132	08/11/2010	6447
R127BP	05/28/2010	Revisions and Re-issuance of Audiology Policies - Rescinded and replaced by Transmittal 129	07/28/2010	6447
R126BP	05/21/2010	Cardiac Rehabilitation and Intensive Cardiac Rehabilitation	10042010	6850

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Rev #	Issue Date	Subject	Impl Date	CR#
R124BP	05/07/2010	Pulmonary Rehabilitation (PR) Services	10/04/2010	6823
R123BP	04/30/2010	Determining Self-Administration of Drug or Biological	07/30/2010	6950
R120BP	01/29/2010	Revision of Definition of Compendia as Authoritative Source for Use in the Determination of a Medically-Accepted Indication of Drugs/Biologicals Used Off-Label in Anti-Cancer Chemotherapeutic Regimens	03/01/2010	6806
R118BP	12/18/2009	Expansion of Telelhealth Services for CY 2010	01/04/2010	6705
R117BP	12/18/2009	Coverage of Kidney Disease Patient Education Services	04/05/2010	6557
R116BP	12/11/2009	January 2010 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/04/2010	6751
R109BP	08/07/2009	Diabetes Self-Management Training (DSMT) Certified Diabetic Educator	09/08/2009	6510
R108BP	07/31/2009	New Reporting Requirements for the Quarterly Opt Out Report in Contractor Reporting of Operational Workload Data (CROWD)	01/04/2010	6562
R106BP	04/24/2009	Speech-Language Pathology Practice Payment Policy	07/06/2009	6381
R105BP	04/24/2009	List of Medicare Telehealth Services	05/26/2009	6458
R104BP	03/13/2009	April 2009 Update to the ASC Payment System; Summary of Payment Policy Changes/Manual Revisions	04/06/2009	6424
R99BP	12/24/2008	Expansion of Medicare Telehealth Services	01/05/2009	6130
R97BP	11/14/2008	Adding Certain Entities as Originating Sites for Payment of Telehealth Services-Section 149 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)	01/05/2009	6215
R96BP	10/24/2008	Compendia as Authoritative Sources for Use in the Determination of a “Medically Accepted Indication” of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic	11/25/2008	6191

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Rev #	Issue Date	Subject	Impl Date	CR#
		Regimen		
R94BP	08/29/2008	Physician Signature Requirements for Diagnostic Tests	09/30/2008	6100
R93BP	07/25/2008	Screening DNA Stool Test for Colorectal Cancer	08/25/2008	6145
R92BP	06/27/2008	Private Contracting/Opting Out of Medicare	09/29/2008	6081
R91BP	06/20/2008	Self-Administered Drug Exclusion Lists	07/21/2008	5988
R88BP	05/07/2008	Therapy Personnel Qualifications and Policies Effective January 1, 2008	06/09/2008	5921
R87BP	05/02/2008	Incident to Policy Update - Rescinded	06/02/2008	5288
R86BP	04/18/2008	Payments for Medicare Part B Services Furnished by Certain Indian Health Service (IHS) Hospitals and Clinics	05/19/2008	5807
R85BP	02/29/2008	Psychological and Neuropsychological Tests	12/28/2006	5204
R84BP	02/29/2008	Update to Audiology Policies	04/07/2008	5717
R81BP	02/07/2008	Process for Amending the List of Compendia for Determination of Medically-Accepted Indications for Off-Label Uses of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen	03/07/2008	5870
R80BP	01/11/2008	Requirements for Ordering and Following Orders for Diagnostic Tests – Replaced by Transmittal 80	11/19/2007	5743
R79BP	10/19/2007	Requirements for Ordering and Following Orders for Diagnostic Tests – Replaced by Transmittal 80	11/19/2007	5743
R78BP	09/21/2007	Unlabeled Use for Anti-Cancer Drugs – Medical Literature Used to Determine Medically Accepted Indications for Drugs and Biologicals Used in Anti-Cancer Treatment	10/22/2007	5729
R77BP	08/29/2007	Testing and Implementation of 2008 Ambulatory Surgical Center (ASC) Payment System Changes	01/07/2008	5680

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R76BP	07/20/2007	Testing and Implementation of 2008 Ambulatory Surgical Center (ASC) Payment System Changes – Replaced by Transmittal 77	01/07/2008	5680
R75BP	08/17/2007	Nurse Practitioner (NP) Services and Clinical Nurse Specialist (CNS) Services	11/19/2007	5639
R74BP	06/29/2007	Medicare Telehealth Services	01/07/2008	5628
R72BP	05/25/2007	Guidelines for Payment of Diabetes Self-Management Training (DSMT)	07/02/2007	5433
R71BP	05/25/2007	Clarification of Manual Instruction Regarding the Scope of Portable X-Ray Benefit	07/02/2007	5536
R70BP	05/11/2007	Bone Mass Measurements (BMMs)	07/02/2007	5521
R64BP	01/19/2007	Guidelines for Payment of Diabetes Self-Management Training (DSMT) – Replaced by Transmittal 72	07/02/2007	5433
R63BP	12/29/2006	Outpatient Therapy Cap Exceptions Process for Calendar Year (CY) 2007	01/29/2007	5478
R62BP	12/22/2006	Private Contracting-Definition of Physician/Practitioner	04/02/2007	5426
R60BP	11/09/2006	Outpatient Therapy Cap Clarification	01/02/2007	5271
R55BP	09/29/2006	Psychological and Neuropsychological Tests – Rescinded and Replaced by Transmittal 85	12/28/2006	5204
R53BP	07/07/2006	Medicare Telehealth Services Update	08/07/2006	5122
R52BP	06/30/2006	Therapy Caps Exception Process	03/13/2006	4364
R51BP	06/23/2006	Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests; Clinical Psychologist Services	09/21/2006	4400
R48BP	03/24/2006	Expansion of Glaucoma Screening Services	04/03/2006	4365
R47BP	02/15/2006	Therapy Caps Exception Process	03/13/2006	4364
R46BP	02/13/2006	Therapy Caps Exception Process - Rescinded and replaced by Transmittal 47	03/13/2006	4364

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R43BP	12/23/2005	List of Medicare Telehealth Services	04/03/2006	4204
R37BP	08/12/2005	Conforming Changes for Change Request 3648 to Pub. 100-02	09/12/2005	3912
R36BP	06/24/2005	Pub. 100-02, Chapter 15, Sections 220 and 230 Therapy Services	06/06/2005	3648
R34BP	05/06/2005	Pub. 100-02, Chapter 15, Sections 220 and 230 Therapy Services	06/06/2005	3648
R31BP	04/01/2005	List of Medicare Telehealth Services	05/02/2005	3747
R30BP	02/18/2005	Policy for Repair and Replacement of Durable Medical Equipment (DME)	N/A	3693
R24BP	10/29/2004	Revision of Section 300.5.1, Chapter 15 of the Medicare Benefit Policy Manual to include 22x TOB as an applicable TOB for Diabetes Self-Management Training	01/03/2005	3531
R23BP	10/08/2004	Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063	10/04/2004	3449
R20BP	09/17/2004	Providing Information for Incident to Services. Full Replacement of CR CR 3242. - Rescinded	04/01/2005	3460
R18BP	09/03/2004	Revised Requirements for Chiropractic Billing of Active/Corrective Treatment and Maintenance Therapy. Full Replacement of CR 3063	10/04/2004	3449
R17BP	06/18/2004	Providing Information for Incident to Services. - Replaced by Transmittal 20-CR 3460.	10/04/2004	3242
R13BP	05/28/2004	Diabetes Self Management Training Services	06/28/2004	3185
R12BP	05/28/2004	Chiropractor's Services	10/04/2004	3063
R09BP	04/23/2004	Arrangements for Physical, Occupational, and Speech Language Pathology Services (PT, OT, SLP)	05/24/2004	3134
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R05BP	01/09/2004	Coverage of Outpatient Physical Therapy, Occupational Therapy and Speech-Language Pathology Services Under Medical Insurance	03/15/2004	2859 & 2779
R04BP	01/02/2004	Dentists, podiatrists, and optometrists are added to the definition/list of physicians who may opt out of Medicare	02/02/2004	3016
R03BP	12/19/2003	Coverage of iFOBT	01/05/2004	2996
R01BP	10/01/2003	Introduction to the Benefit Policy Manual	N/A	N/A

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