

Department of Health and Human Services, the Medicare Beneficiary Ombudsman, a sub-contractor, a carrier, a fiscal intermediary, and a Medicare administrative contractor under section 1395kk-1 of this title) through the date on which the complaint is resolved. The system shall be able to report and initiate appropriate interventions and monitoring based on substantial complaints and to guide quality improvement.

(b) Model electronic complaint form

The Secretary shall develop a model electronic complaint form to be used for reporting plan complaints under the system. Such form shall be prominently displayed on the front page of the Medicare.gov Internet website and on the Internet website of the Medicare Beneficiary Ombudsman.

(c) Annual reports by the Secretary

The Secretary shall submit to Congress annual reports on the system. Such reports shall include an analysis of the number and types of complaints reported in the system, geographic variations in such complaints, the timeliness of agency or plan responses to such complaints, and the resolution of such complaints.

(d) Definitions

In this section:

(1) MA-PD plan

The term “MA-PD plan” has the meaning given such term in section 1395w-151(a)(9) of this title.

(2) Prescription drug plan

The term “prescription drug plan” has the meaning given such term in section 1395w-151(a)(14) of this title.

(3) Secretary

The term “Secretary” means the Secretary of Health and Human Services.

(4) System

The term “system” means the plan complaint system developed and maintained under subsection (a).

(Pub. L. 111-148, title III, §3311, Mar. 23, 2010, 124 Stat. 475.)

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Social Security Act which comprises this chapter.

PART E—MISCELLANEOUS PROVISIONS

CODIFICATION

Pub. L. 108-173, title I, §101(a)(1), Dec. 8, 2003, 117 Stat. 2071, redesignated part D of this subchapter as part E.

Pub. L. 105-33, title IV, §4001, Aug. 5, 1997, 111 Stat. 275, redesignated part C of this subchapter as part D.

§ 1395x. Definitions

For purposes of this subchapter—

(a) Spell of illness

The term “spell of illness” with respect to any individual means a period of consecutive days—

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such

individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1395i-3(a)(1) of this title or subsection (y)(1).

(b) Inpatient hospital services

The term “inpatient hospital services” means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however—

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by—

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association, or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American Dental Association, or in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or

(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this subchapter for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this subchapter.

(c) Inpatient psychiatric hospital services

The term “inpatient psychiatric hospital services” means inpatient hospital services furnished to an inpatient of a psychiatric hospital.

(d) Supplier

The term “supplier” means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this subchapter.

(e) Hospital

The term “hospital” (except for purposes of sections 1395f(d), 1395f(f), and 1395n(b) of this title, subsection (a)(2) of this section, paragraph (7) of this subsection, and subsection (i) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this subchapter must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and (B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;

(8) has in effect an overall plan and budget that meets the requirements of subsection (z); and

(9) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1395f(d) and 1395n(b) of this title (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1395f(f)(2) of this title, and subsection (i) of this section, such term includes any institution which (i) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in subsection (j)(1)(A) and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of subsection (r), to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1395f(f)(1) of this title, such term includes an institution which (i) is a hospital for purposes of sections 1395f(d), 1395f(f)(2), and 1395n(b) of this title and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1395bb(a) of this title, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.¹ Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2), include any institution which is primarily for the care and treatment of mental diseases unless it is a psychiatric hospital (as defined in subsection (f)). The term “hospital” also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1395i-5 of this title. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1395bb of this title. The term “hospital” also includes a facil-

¹ So in original.

ity of fifty beds or less which is located in an area determined by the Secretary to meet the definition relating to a rural area described in subparagraph (A) of paragraph (5) of this subsection and which meets the other requirements of this subsection, except that—

(A) with respect to the requirements for nursing services applicable after December 31, 1978, such requirements shall provide for temporary waiver of the requirements, for such period as the Secretary deems appropriate, where (i) the facility's failure to fully comply with the requirements is attributable to a temporary shortage of qualified nursing personnel in the area in which the facility is located, (ii) a registered professional nurse is present on the premises to render or supervise the nursing service provided during at least the regular daytime shift, and (iii) the Secretary determines that the employment of such nursing personnel as are available to the facility during such temporary period will not adversely affect the health and safety of patients;

(B) with respect to the health and safety requirements promulgated under paragraph (9), such requirements shall be applied by the Secretary to a facility herein defined in such manner as to assure that personnel requirements take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which such facility is located, and the scope of services rendered by such facility; and the Secretary, by regulations, shall provide for the continued participation of such a facility where such personnel requirements are not fully met, for such period as the Secretary determines that (i) the facility is making good faith efforts to fully comply with the personnel requirements, (ii) the employment by the facility of such personnel as are available to the facility will not adversely affect the health and safety of patients, and (iii) if the Secretary has determined that because of the facility's waiver under this subparagraph the facility should limit its scope of services in order not to adversely affect the health and safety of the facility's patients, the facility is so limiting the scope of services it provides; and

(C) with respect to the fire and safety requirements promulgated under paragraph (9), the Secretary (i) may waive, for such period as he deems appropriate, specific provisions of such requirements which if rigidly applied would result in unreasonable hardship for such a facility and which, if not applied, would not jeopardize the health and safety of patients, and (ii) may accept a facility's compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients.

The term "hospital" does not include, unless the context otherwise requires, a critical access hospital (as defined in subsection (mm)(1)).

(f) Psychiatric hospital

The term "psychiatric hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (9) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A; and

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a "psychiatric hospital".

(g) Outpatient occupational therapy services

The term "outpatient occupational therapy services" has the meaning given the term "outpatient physical therapy services" in subsection (p), except that "occupational" shall be substituted for "physical" each place it appears therein.

(h) Extended care services

The term "extended care services" means the following items and services furnished to an inpatient of a skilled nursing facility and (except as provided in paragraphs (3), (6), and (7)) by such skilled nursing facility—

(1) nursing care provided by or under the supervision of a registered professional nurse;

(2) bed and board in connection with the furnishing of such nursing care;

(3) physical or occupational therapy or speech-language pathology services furnished by the skilled nursing facility or by others under arrangements with them made by the facility;

(4) medical social services;

(5) such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the skilled nursing facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;

(6) medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l)), under a teaching program of such hospital approved as provided in the last sentence of subsection (b), and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and

(7) such other services necessary to the health of the patients as are generally provided by skilled nursing facilities, or by others under arrangements with them made by the facility;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

(i) Post-hospital extended care services

The term "post-hospital extended care services" means extended care services furnished an individual after transfer from a hospital in which he was an inpatient for not less than 3 consecutive days before his discharge from the hospital in connection with such transfer. For purposes of the preceding sentence, items and services shall be deemed to have been furnished to an individual after transfer from a hospital, and he shall be deemed to have been an inpatient in the hospital immediately before transfer therefrom, if he is admitted to the skilled nursing facility (A) within 30 days after discharge from such hospital, or (B) within such time as it would be medically appropriate to begin an active course of treatment, in the case of an individual whose condition is such that skilled nursing facility care would not be medically appropriate within 30 days after discharge from a hospital; and an individual shall be deemed not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

(j) Skilled nursing facility

The term "skilled nursing facility" has the meaning given such term in section 1395i-3(a) of this title.

(k) Utilization review

A utilization review plan of a hospital or skilled nursing facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this subchapter and if it provides—

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians (of which at least two must be physicians described in subsection (r)(1) of this section), with or without participation of other professional personnel, or (B) a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the hospitals and skilled nursing facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary;

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as

promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to subchapter XIX are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this subchapter that the procedures established pursuant to subchapter XIX be utilized instead of the procedures required by this section.

(l) Agreements for transfer between skilled nursing facilities and hospitals

A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that—

(1) transfer of patients will be effected between the hospital and the skilled nursing facility whenever such transfer is medically appropriate as determined by the attending physician; and

(2) there will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.

Any skilled nursing facility which does not have such an agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1395aa of this title is in effect (or, in the case of a State in which no such agency has an agreement under section 1395aa of this title, by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (2), shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to assuring extended care services for persons in the community who are eligible for

payments with respect to such services under this subchapter.

(m) Home health services

The term “home health services” means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual’s home—

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical or occupational therapy or speech-language pathology services;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide who has successfully completed a training program approved by the Secretary;

(5) medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs and biologicals) and durable medical equipment and applicable disposable devices (as defined in section 1395m(s)(2) of this title) while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or skilled nursing facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and—

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A),

but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital and home infusion therapy (as defined in subsection (iii)(i)). For purposes of paragraphs (1) and (4), the term “part-time or intermittent services” means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each

week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1395f(a)(2)(C) and 1395n(a)(2)(A) of this title, “intermittent” means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).

(n) Durable medical equipment

The term “durable medical equipment” includes iron lungs, oxygen tents, hospital beds, and wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual’s medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient’s home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1395i-3(a)(1) of this title), whether furnished on a rental basis or purchased, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual’s use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations) and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment. With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.

(o) Home health agency

The term “home health agency” means a public agency or private organization, or a subdivision of such an agency or organization, which—

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;

(5) has in effect an overall plan and budget that meets the requirements of subsection (z);

(6) meets the conditions of participation specified in section 1395bbb(a) of this title and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

(A) in a form specified by the Secretary and in an amount that is not less than the minimum of \$50,000; and

(B) that the Secretary determines is commensurate with the volume of payments to the home health agency; and

(8) meets such additional requirements (including conditions relating to bonding or establishing of escrow accounts as the Secretary finds necessary for the financial security of the program) as the Secretary finds necessary for the effective and efficient operation of the program;

except that for purposes of part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases. The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.

(p) Outpatient physical therapy services

The term “outpatient physical therapy services” means physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient—

(1) who is under the care of a physician (as defined in paragraph (1), (3), or (4) of subsection (r)), and

(2) with respect to whom a plan prescribing the type, amount, and duration of physical therapy services that are to be furnished such individual has been established by a physician (as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined);

excluding, however—

(3) any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital; and

(4) any such service—

(A) if furnished by a clinic or rehabilitation agency, or by others under arrangements with such clinic or agency, unless such clinic or rehabilitation agency—

(i) provides an adequate program of physical therapy services for outpatients and has the facilities and personnel required for such program or required for the supervision of such a program, in accordance with such requirements as the Secretary may specify,

(ii) has policies, established by a group of professional personnel, including one or

more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

(iv) if such clinic or agency is situated in a State in which State or applicable local law provides for the licensing of institutions of this nature, (I) is licensed pursuant to such law, or (II) is approved by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

(v) meets such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary, and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000, or

(B) if furnished by a public health agency, unless such agency meets such other conditions relating to health and safety of individuals who are furnished services by such agency on an outpatient basis, as the Secretary may find necessary.

The term “outpatient physical therapy services” also includes physical therapy services furnished an individual by a physical therapist (in his office or in such individual’s home) who meets licensing and other standards prescribed by the Secretary in regulations, otherwise than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, if the furnishing of such services meets such conditions relating to health and safety as the Secretary may find necessary. In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an inpatient of a hospital or extended care facility. Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this subchapter, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician. The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.

(q) Physicians’ services

The term “physicians’ services” means professional services performed by physicians, including surgery, consultation, and home, office, and institutional calls (but not including services described in subsection (b)(6)).

(r) Physician

The term “physician”, when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteop-

athy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1301(a)(7) of this title), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of subsections (s)(1) and (s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1395y(a)(4) of this title and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1395y(a)(4) of this title) are furnished.

(s) Medical and other health services

The term “medical and other health services” means any of the following items or services:

(1) physicians’ services;

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician’s professional service, of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills (or would have been so included but for the application of section 1395w-3b of this title);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians’ services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1395rr(b)(14)(B) of this title), including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1395rr(b)(14) of this title to an individual with acute kidney injury (as defined in section 1395m(r)(2) of this title);

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in subsection (r)(1), for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5)) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician’s service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2)), and such services and supplies furnished as an incident to such clinical psychologist’s services or clinical social worker’s services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician’s service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this subchapter;

(K)(i) services which would be physicians’ services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be

covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;²

(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2));

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo));

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp)); and³

(S) diabetes outpatient self-management training services (as defined in subsection (qq));

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with

a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who—

(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

(ii) is not receiving maintenance dialysis for which payment is made under section 1395rr of this title; and

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww));

(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));

(Y) diabetes screening tests (as defined in subsection (yy));

(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bb)) for an individual—

(i) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (as defined in subsection (ww)(1));

(ii) who has not been previously furnished such an ultrasound screening under this subchapter; and

(iii) who—

(I) has a family history of abdominal aortic aneurysm; or

(II) manifests risk factors included in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms;

(BB) additional preventive services (described in subsection (ddd)(1));

(CC) items and services furnished under a cardiac rehabilitation program (as defined in subsection (eee)(1)) or under a pulmonary rehabilitation program (as defined in subsection (fff)(1));

(DD) items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4));

(EE) kidney disease education services (as defined in subsection (ggg));

(FF) personalized prevention plan services (as defined in subsection (hhh));

(GG) home infusion therapy (as defined in subsection (iii)(1)); and

(HH) opioid use disorder treatment services (as defined in subsection (jjj)).

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provi-

² So in original. Probably should be followed by "and".

³ So in original. The word "and" probably should not appear.

sional certificate) issued under section 354 of the Public Health Service Act [42 U.S.C. 263b]), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but, subject to section 1395m(l)(14) of this title, only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration, and subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if—

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj));

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr)).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title) shall be included within paragraph (3) unless such laboratory—

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act [42 U.S.C. 263a]; and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1395f(d) of this title shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

(t) Drugs and biologicals

(1) The term “drugs” and the term “biologicals”, except for purposes of subsection (m)(5) of this section and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

(2)(A) For purposes of paragraph (1), the term “drugs” also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).

(B) In subparagraph (A), the term “medically accepted indication”, with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and

(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary

Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or

(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has⁴ a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

(u) Provider of services

The term “provider of services” means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1395f(g) and section 1395n(e) of this title, a fund.

(v) Reasonable costs

(1)(A) The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs for various types or classes of institutions, agencies, and services; except that in any case to which paragraph (2) or (3) applies, the amount of the payment determined under such paragraph with respect to the services involved shall be considered the reasonable cost of such services. In prescribing the regulations referred to in the preceding sentence, the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. Such regulations may provide for determination of the costs of services on a per diem, per unit, per capita, or other basis, may provide for using different methods in different circumstances, may provide for the use of estimates of costs of particular items or services, may provide for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on esti-

mates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this subchapter, and may provide for the use of charges or a percentage of charges where this method reasonably reflects the costs. Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this subchapter) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this subchapter will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs proves to be either inadequate or excessive.

(B) In the case of extended care services, the regulations under subparagraph (A) shall not include provision for specific recognition of a return on equity capital.

(C) Where a hospital has an arrangement with a medical school under which the faculty of such school provides services at such hospital, an amount not in excess of the reasonable cost of such services to the medical school shall be included in determining the reasonable cost to the hospital of furnishing services—

(i) for which payment may be made under part A, but only if—

(I) payment for such services as furnished under such arrangement would be made under part A to the hospital had such services been furnished by the hospital, and

(II) such hospital pays to the medical school at least the reasonable cost of such services to the medical school, or

(ii) for which payment may be made under part B, but only if such hospital pays to the medical school at least the reasonable cost of such services to the medical school.

(D) Where (i) physicians furnish services which are either inpatient hospital services (including services in conjunction with the teaching programs of such hospital) by reason of paragraph (7) of subsection (b) or for which entitlement exists by reason of clause (II) of section 1395k(a)(2)(B)(i) of this title, and (ii) such hospital (or medical school under arrangement with such hospital) incurs no actual cost in the furnishing of such services, the reasonable cost of such services shall (under regulations of the Secretary) be deemed to be the cost such hospital or medical school would have incurred had it paid a salary to such physicians rendering such services approximately equivalent to the average salary paid to all physicians employed by such hospital (or if such employment does not exist, or is minimal in such hospital, by similar hospitals in a geographic area of suffi-

⁴ So in original. Probably should be “have”.

cient size to assure reasonable inclusion of sufficient physicians in development of such average salary).

(E) Such regulations may, in the case of skilled nursing facilities in any State, provide for the use of rates, developed by the State in which such facilities are located, for the payment of the cost of skilled nursing facility services furnished under the State's plan approved under subchapter XIX (and such rates may be increased by the Secretary on a class or size of institution or on a geographical basis by a percentage factor not in excess of 10 percent to take into account determinable items or services or other requirements under this subchapter not otherwise included in the computation of such State rates), if the Secretary finds that such rates are reasonably related to (but not necessarily limited to) analyses undertaken by such State of costs of care in comparable facilities in such State. Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this subchapter) of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1395i-3 of this title (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(F) Such regulations shall require each provider of services (other than a fund) to make reports to the Secretary of information described in section 1320a(a) of this title in accordance with the uniform reporting system (established under such section) for that type of provider.

(G)(i) In any case in which a hospital provides inpatient services to an individual that would constitute post-hospital extended care services if provided by a skilled nursing facility and a quality improvement organization (or, in the absence of such a qualified organization, the Secretary or such agent as the Secretary may designate) determines that inpatient hospital services for the individual are not medically necessary but post-hospital extended care services for the individual are medically necessary and such extended care services are not otherwise available to the individual (as determined in accordance with criteria established by the Secretary) at the time of such determination, payment for such services provided to the individual shall continue to be made under this subchapter at the payment rate described in clause (ii) during the period in which—

(I) such post-hospital extended care services for the individual are medically necessary and not otherwise available to the individual (as so determined),

(II) inpatient hospital services for the individual are not medically necessary, and

(III) the individual is entitled to have payment made for post-hospital extended care services under this subchapter,

except that if the Secretary determines that there is not an excess of hospital beds in such

hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital, such payment shall be made (during such period) on the basis of the amount otherwise payable under part A with respect to inpatient hospital services.

(ii)(I) Except as provided in subclause (II), the payment rate referred to in clause (i) is a rate equal to the estimated adjusted State-wide average rate per patient-day paid for services provided in skilled nursing facilities under the State plan approved under subchapter XIX for the State in which such hospital is located, or, if the State in which the hospital is located does not have a State plan approved under subchapter XIX, the estimated adjusted State-wide average allowable costs per patient-day for extended care services under this subchapter in that State.

(II) If a hospital has a unit which is a skilled nursing facility, the payment rate referred to in clause (i) for the hospital is a rate equal to the lesser of the rate described in subclause (I) or the allowable costs in effect under this subchapter for extended care services provided to patients of such unit.

(iii) Any day on which an individual receives inpatient services for which payment is made under this subparagraph shall, for purposes of this chapter (other than this subparagraph), be deemed to be a day on which the individual received inpatient hospital services.

(iv) In determining under clause (i), in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, such determination shall be made on the basis of only the public hospitals (including the hospital) which are in the area of the hospital and which are under common ownership with that hospital.

(H) In determining such reasonable cost with respect to home health agencies, the Secretary may not include—

(i) any costs incurred in connection with bonding or establishing an escrow account by any such agency as a result of the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8);

(ii) in the case of home health agencies to which the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply, any costs attributed to interest charged such an agency in connection with amounts borrowed by the agency to repay overpayments made under this subchapter to the agency, except that such costs may be included in reasonable cost if the Secretary determines that the agency was acting in good faith in borrowing the amounts;

(iii) in the case of contracts entered into by a home health agency after December 5, 1980, for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract which is entered into for a period exceeding five years; and

(iv) in the case of contracts entered into by a home health agency before December 5, 1980, for the purpose of having services furnished

for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract, which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

(I) In determining such reasonable cost, the Secretary may not include any costs incurred by a provider with respect to any services furnished in connection with matters for which payment may be made under this subchapter and furnished pursuant to a contract between the provider and any of its subcontractors which is entered into after December 5, 1980, and the value or cost of which is \$10,000 or more over a twelve-month period unless the contract contains a clause to the effect that—

(i) until the expiration of four years after the furnishing of such services pursuant to such contract, the subcontractor shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the contract, and books, documents and records of such subcontractor that are necessary to certify the nature and extent of such costs, and

(ii) if the subcontractor carries out any of the duties of the contract through a subcontract, with a value or cost of \$10,000 or more over a twelve-month period, with a related organization, such subcontract shall contain a clause to the effect that until the expiration of four years after the furnishing of such services pursuant to such subcontract, the related organization shall make available, upon written request by the Secretary, or upon request by the Comptroller General, or any of their duly authorized representatives, the subcontract, and books, documents and records of such organization that are necessary to verify the nature and extent of such costs.

The Secretary shall prescribe in regulation⁵ criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontracts under this subparagraph.

(J) Such regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities.

(K)(i) The Secretary shall issue regulations that provide, to the extent feasible, for the establishment of limitations on the amount of any costs or charges that shall be considered reasonable with respect to services provided on an outpatient basis by hospitals (other than bona fide emergency services as defined in clause (ii)) or clinics (other than rural health clinics), which are reimbursed on a cost basis or on the basis of cost related charges, and by physicians utilizing such outpatient facilities. Such limitations shall be reasonably related to the charges in the same area for similar services provided in physi-

cians' offices. Such regulations shall provide for exceptions to such limitations in cases where similar services are not generally available in physicians' offices in the area to individuals entitled to benefits under this subchapter.

(ii) For purposes of clause (i), the term "bona fide emergency services" means services provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(I) placing the patient's health in serious jeopardy;

(II) serious impairment to bodily functions; or

(III) serious dysfunction of any bodily organ or part.

(L)(i) The Secretary, in determining the amount of the payments that may be made under this subchapter with respect to services furnished by home health agencies, may not recognize as reasonable (in the efficient delivery of such services) costs for the provision of such services by an agency to the extent these costs exceed (on the aggregate for the agency) for cost reporting periods beginning on or after—

(I) July 1, 1985, and before July 1, 1986, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies,

(II) July 1, 1986, and before July 1, 1987, 115 percent of such mean,

(III) July 1, 1987, and before October 1, 1997, 112 percent of such mean,

(IV) October 1, 1997, and before October 1, 1998, 105 percent of the median of the labor-related and nonlabor per visit costs for freestanding home health agencies, or

(V) October 1, 1998, 106 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis. The Secretary may provide for such exemptions and exceptions to such limitation as he deems appropriate.

(iii) Not later than July 1, 1991, and annually thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, or on or after July 1, 1997, and before October 1, 1997), the Secretary shall establish limits under this subparagraph for cost reporting periods beginning on or after such date by utilizing the area wage index applicable under section 1395ww(d)(3)(E) of this title and determined using the survey of the most recent available wages and wage-related costs of hospitals located in the geographic area in which the home health service is furnished (determined without regard to whether such hospitals have been reclassified to a new geographic area pursuant to section 1395ww(d)(8)(B) of this title, a decision of the Medicare Geographic Classification Review Board under section 1395ww(d)(10) of this title, or a decision of the Secretary).

(iv) In establishing limits under this subparagraph for cost reporting periods beginning after

⁵ So in original. Probably should be "regulations".

September 30, 1997, the Secretary shall not take into account any changes in the home health market basket, as determined by the Secretary, with respect to cost reporting periods which began on or after July 1, 1994, and before July 1, 1996.

(v) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, subject to clause (viii)(I), the Secretary shall provide for an interim system of limits. Payment shall not exceed the costs determined under the preceding provisions of this subparagraph or, if lower, the product of—

(I) an agency-specific per beneficiary annual limitation calculated based 75 percent on 98 percent of the reasonable costs (including non-routine medical supplies) for the agency's 12-month cost reporting period ending during fiscal year 1994, and based 25 percent on 98 percent of the standardized regional average of such costs for the agency's census division, as applied to such agency, for cost reporting periods ending during fiscal year 1994, such costs updated by the home health market basket index; and

(II) the agency's unduplicated census count of patients (entitled to benefits under this subchapter) for the cost reporting period subject to the limitation.

(vi) For services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1997, the following rules apply:

(I) For new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994 subject to clauses (viii)(II) and (viii)(III), the per beneficiary limitation shall be equal to the median of these limits (or the Secretary's best estimates thereof) applied to other home health agencies as determined by the Secretary. A home health agency that has altered its corporate structure or name shall not be considered a new provider for this purpose.

(II) For beneficiaries who use services furnished by more than one home health agency, the per beneficiary limitations shall be prorated among the agencies.

(vii)(I) Not later than January 1, 1998, the Secretary shall establish per visit limits applicable for fiscal year 1998, and not later than April 1, 1998, the Secretary shall establish per beneficiary limits under clause (v)(I) for fiscal year 1998.

(II) Not later than August 1 of each year (beginning in 1998) the Secretary shall establish the limits applicable under this subparagraph for services furnished during the fiscal year beginning October 1 of the year.

(viii)(I) In the case of a provider with a 12-month cost reporting period ending in fiscal year 1994, if the limit imposed under clause (v) (determined without regard to this subclause) for a cost reporting period beginning during or after fiscal year 1999 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by $\frac{1}{3}$ of such difference.

(II) Subject to subclause (IV), for new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994, but for which the first cost reporting period begins before fiscal year 1999, for cost reporting periods beginning during or after fiscal year 1999, the per beneficiary limitation described in clause (vi)(I) shall be equal to the median described in such clause (determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent").

(III) Subject to subclause (IV), in the case of a new provider for which the first cost reporting period begins during or after fiscal year 1999, the limitation applied under clause (vi)(I) (but only with respect to such provider) shall be equal to 75 percent of the median described in clause (vi)(I).

(IV) In the case of a new provider or a provider without a 12-month cost reporting period ending in fiscal year 1994, subclause (II) shall apply, instead of subclause (III), to a home health agency which filed an application for home health agency provider status under this subchapter before September 15, 1998, or which was approved as a branch of its parent agency before such date and becomes a subunit of the parent agency or a separate agency on or after such date.

(V) Each of the amounts specified in subclauses (I) through (III) are such amounts as adjusted under clause (iii) to reflect variations in wages among different areas.

(ix) Notwithstanding the per beneficiary limit under clause (viii), if the limit imposed under clause (v) (determined without regard to this clause) for a cost reporting period beginning during or after fiscal year 2000 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to "98 percent" were a reference to "100 percent"), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 2 percent.

(x) Notwithstanding any other provision of this subparagraph, in updating any limit under this subparagraph by a home health market basket index for cost reporting periods beginning during each of fiscal years 2000, 2002, and 2003, the update otherwise provided shall be reduced by 1.1 percentage points. With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.

(M) Such regulations shall provide that costs respecting care provided by a provider of services, pursuant to an assurance under title VI or XVI of the Public Health Service Act [42 U.S.C. 291 et seq., 300q et seq.] that the provider will make available a reasonable volume of services to persons unable to pay therefor, shall not be allowable as reasonable costs.

(N) In determining such reasonable costs, costs incurred for activities directly related to influencing employees respecting unionization may not be included.

(O)(i) In establishing an appropriate allowance for depreciation and for interest on capital indebtedness with respect to an asset of a provider of services which has undergone a change of ownership, such regulations shall provide, ex-

cept as provided in clause (iii), that the valuation of the asset after such change of ownership shall be the historical cost of the asset, as recognized under this subchapter, less depreciation allowed, to the owner of record as of August 5, 1997 (or, in the case of an asset not in existence as of August 5, 1997, the first owner of record of the asset after August 5, 1997).

(ii) Such regulations shall not recognize, as reasonable in the provision of health care services, costs (including legal fees, accounting and administrative costs, travel costs, and the costs of feasibility studies) attributable to the negotiation or settlement of the sale or purchase of any capital asset (by acquisition or merger) for which any payment has previously been made under this subchapter.

(iii) In the case of the transfer of a hospital from ownership by a State to ownership by a nonprofit corporation without monetary consideration, the basis for capital allowances to the new owner shall be the book value of the hospital to the State at the time of the transfer.

(P) If such regulations provide for the payment for a return on equity capital (other than with respect to costs of inpatient hospital services), the rate of return to be recognized, for determining the reasonable cost of services furnished in a cost reporting period, shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(Q) Except as otherwise explicitly authorized, the Secretary is not authorized to limit the rate of increase on allowable costs of approved medical educational activities.

(R) In determining such reasonable cost, costs incurred by a provider of services representing a beneficiary in an unsuccessful appeal of a determination described in section 1395ff(b) of this title shall not be allowable as reasonable costs.

(S)(i) Such regulations shall not include provision for specific recognition of any return on equity capital with respect to hospital outpatient departments.

(ii)(I) Such regulations shall provide that, in determining the amount of the payments that may be made under this subchapter with respect to all the capital-related costs of outpatient hospital services, the Secretary shall reduce the amounts of such payments otherwise established under this subchapter by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1990, by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1991, and by 10 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1992 through 1999 and until the first date that the prospective payment system under section 1395(t) of this title is implemented.

(II) The Secretary shall reduce the reasonable cost of outpatient hospital services (other than the capital-related costs of such services) otherwise determined pursuant to section 1395(a)(2)(B)(i)(I) of this title by 5.8 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1991 through 1999 and until the first date that

the prospective payment system under section 1395(t) of this title is implemented.

(III) Subclauses (I) and (II) shall not apply to payments with respect to the costs of hospital outpatient services provided by any hospital that is a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) or a critical access hospital (as defined in subsection (mm)(1)).

(IV) In applying subclauses (I) and (II) to services for which payment is made on the basis of a blend amount under section 1395(i)(3)(A)(ii) or 1395(n)(1)(A)(ii) of this title, the costs reflected in the amounts described in sections 1395(i)(3)(B)(i)(I) and 1395(n)(1)(B)(i)(I) of this title, respectively, shall be reduced in accordance with such subclause.⁶

(T) In determining such reasonable costs for hospitals, no reduction in copayments under section 1395(t)(8)(B) of this title shall be treated as a bad debt and the amount of bad debts otherwise treated as allowable costs which are attributable to the deductibles and coinsurance amounts under this subchapter shall be reduced—

(i) for cost reporting periods beginning during fiscal year 1998, by 25 percent of such amount otherwise allowable,

(ii) for cost reporting periods beginning during fiscal year 1999, by 40 percent of such amount otherwise allowable,

(iii) for cost reporting periods beginning during fiscal year 2000, by 45 percent of such amount otherwise allowable,

(iv) for cost reporting periods beginning during fiscal years 2001 through 2012, by 30 percent of such amount otherwise allowable, and

(v) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(U) In determining the reasonable cost of ambulance services (as described in subsection (s)(7)) provided during fiscal year 1998, during fiscal year 1999, and during so much of fiscal year 2000 as precedes January 1, 2000, the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year (after application of this subparagraph), increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the fiscal year involved reduced by 1.0 percentage point. For ambulance services provided after June 30, 1998, the Secretary may provide that claims for such services must include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(V) In determining such reasonable costs for skilled nursing facilities and (beginning with respect to cost reporting periods beginning during fiscal year 2013) for covered skilled nursing services described in section 1395yy(e)(2)(A) of this title furnished by hospital providers of extended care services (as described in section 1395tt of

⁶ So in original. Probably should be "subclauses."

this title), the amount of bad debts otherwise treated as allowed costs which are attributable to the coinsurance amounts under this subchapter for individuals who are entitled to benefits under part A and—

(i) are not described in section 1396u-5(c)(6)(A)(ii) of this title shall be reduced by—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, 30 percent of such amount otherwise allowable; and

(II) for cost reporting periods beginning during fiscal year 2013 or a subsequent fiscal year, by⁷ 35 percent of such amount otherwise allowable.

(ii) are described in such section—

(I) for cost reporting periods beginning on or after October 1, 2005, but before fiscal year 2013, shall not be reduced;

(II) for cost reporting periods beginning during fiscal year 2013, shall be reduced by 12 percent of such amount otherwise allowable;

(III) for cost reporting periods beginning during fiscal year 2014, shall be reduced by 24 percent of such amount otherwise allowable; and

(IV) for cost reporting periods beginning during a subsequent fiscal year, shall be reduced by 35 percent of such amount otherwise allowable.

(W)(i) In determining such reasonable costs for providers described in clause (ii), the amount of bad debts otherwise treated as allowable costs which are attributable to deductibles and coinsurance amounts under this subchapter shall be reduced—

(I) for cost reporting periods beginning during fiscal year 2013, by 12 percent of such amount otherwise allowable;

(II) for cost reporting periods beginning during fiscal year 2014, by 24 percent of such amount otherwise allowable; and

(III) for cost reporting periods beginning during a subsequent fiscal year, by 35 percent of such amount otherwise allowable.

(ii) A provider described in this clause is a provider of services not described in subparagraph (T) or (V), a supplier, or any other type of entity that receives payment for bad debts under the authority under subparagraph (A).

(2)(A) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations more expensive than semi-private accommodations, the amount taken into account for purposes of payment under this subchapter with respect to such services may not exceed the amount that would be taken into account with respect to such services if furnished in such semi-private accommodations unless the more expensive accommodations were required for medical reasons.

(B) Where a provider of services which has an agreement in effect under this subchapter furnishes to an individual items or services which

are in excess of or more expensive than the items or services with respect to which payment may be made under part A or part B, as the case may be, the Secretary shall take into account for purposes of payment to such provider of services only the items or services with respect to which such payment may be made.

(3) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations other than, but not more expensive than, semi-private accommodations and the use of such other accommodations rather than semi-private accommodations was neither at the request of the patient nor for a reason which the Secretary determines is consistent with the purposes of this subchapter, the amount of the payment with respect to such bed and board under part A shall be the amount otherwise payable under this subchapter for such bed and board furnished in semi-private accommodations minus the difference between the charge customarily made by the hospital or skilled nursing facility for bed and board in semi-private accommodations and the charge customarily made by it for bed and board in the accommodations furnished.

(4) If a provider of services furnishes items or services to an individual which are in excess of or more expensive than the items or services determined to be necessary in the efficient delivery of needed health services and charges are imposed for such more expensive items or services under the authority granted in section 1395cc(a)(2)(B)(ii)⁸ of this title, the amount of payment with respect to such items or services otherwise due such provider in any fiscal period shall be reduced to the extent that such payment plus such charges exceed the cost actually incurred for such items or services in the fiscal period in which such charges are imposed.

(5)(A) Where physical therapy services, occupational therapy services, speech therapy services, or other therapy services or services of other health-related personnel (other than physicians) are furnished under an arrangement with a provider of services or other organization, specified in the first sentence of subsection (p) (including through the operation of subsection (g)) the amount included in any payment to such provider or other organization under this subchapter as the reasonable cost of such services (as furnished under such arrangements) shall not exceed an amount equal to the salary which would reasonably have been paid for such services (together with any additional costs that would have been incurred by the provider or other organization) to the person performing them if they had been performed in an employment relationship with such provider or other organization (rather than under such arrangement) plus the cost of such other expenses (including a reasonable allowance for traveltime and other reasonable types of expense related to any differences in acceptable methods of organization for the provision of such therapy) incurred by such person, as the Secretary may in regulations determine to be appropriate.

⁷ So in original. The word "by" probably should not appear.

⁸ See References in Text note below.

(B) Notwithstanding the provisions of subparagraph (A), if a provider of services or other organization specified in the first sentence of subsection (p) requires the services of a therapist on a limited part-time basis, or only to perform intermittent services, the Secretary may make payment on the basis of a reasonable rate per unit of service, even though such rate is greater per unit of time than salary related amounts, where he finds that such greater payment is, in the aggregate, less than the amount that would have been paid if such organization had employed a therapist on a full- or part-time salary basis.

(6) For purposes of this subsection, the term, “semi-private accommodations” means two-bed, three-bed, or four-bed accommodations.

(7)(A) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1320a-1 of this title.

(B) For further limitations on reasonable cost and determination of payment amounts for operating costs of inpatient hospital services and waivers for certain States, see section 1395ww of this title.

(C) For provisions restricting payment for provider-based physicians’ services and for payments under certain percentage arrangements, see section 1395xx of this title.

(D) For further limitations on reasonable cost and determination of payment amounts for routine service costs of skilled nursing facilities, see subsections (a) through (c) of section 1395yy of this title.

(8) ITEMS UNRELATED TO PATIENT CARE.—Reasonable costs do not include costs for the following—

- (i) entertainment, including tickets to sporting and other entertainment events;
- (ii) gifts or donations;
- (iii) personal use of motor vehicles;
- (iv) costs for fines and penalties resulting from violations of Federal, State, or local laws; and
- (v) education expenses for spouses or other dependents of providers of services, their employees or contractors.

(w) Arrangements for certain services; payments pursuant to arrangements for utilization review activities

(1) The term “arrangements” is limited to arrangements under which receipt of payment by the hospital, critical access hospital, skilled nursing facility, home health agency, or hospice program (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this subchapter, discharges the liability of such individual or any other person to pay for the services.

(2) Utilization review activities conducted, in accordance with the requirements of the program established under part B of subchapter XI of this chapter with respect to services furnished by a hospital or critical access hospital to patients insured under part A of this subchapter or entitled to have payment made for such services under part B of this subchapter or

under a State plan approved under subchapter XIX, by a quality improvement organization designated for the area in which such hospital or critical access hospital is located shall be deemed to have been conducted pursuant to arrangements between such hospital or critical access hospital and such organization under which such hospital or critical access hospital is obligated to pay to such organization, as a condition of receiving payment for hospital or critical access hospital services so furnished under this part or under such a State plan, such amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital or critical access hospital to such patients.

(x) State and United States

The terms “State” and “United States” have the meaning given to them by subsections (h) and (i), respectively, of section 410 of this title.

(y) Extended care in religious nonmedical health care institutions

(1) The term “skilled nursing facility” also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only (except for purposes of subsection (a)(2)) with respect to items and services ordinarily furnished by such an institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1395i-5 of this title.

(2) Notwithstanding any other provision of this subchapter, payment under part A may not be made for services furnished an individual in a skilled nursing facility to which paragraph (1) applies unless such individual elects, in accordance with regulations, for a spell of illness to have such services treated as post-hospital extended care services for purposes of such part; and payment under part A may not be made for post-hospital extended care services—

(A) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) applies after—

- (i) such services have been furnished to him in such a facility for 30 days during such spell, or
- (ii) such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph does not apply; or

(B) furnished an individual during such spell of illness in a skilled nursing facility to which paragraph (1) does not apply after such services have been furnished to him during such spell in a skilled nursing facility to which such paragraph applies.

(3) The amount payable under part A for post-hospital extended care services furnished an individual during any spell of illness in a skilled nursing facility to which paragraph (1) applies shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deduct-

ible for each day before the 31st day on which he is furnished such services in such a facility during such spell (and the reduction under this paragraph shall be in lieu of any reduction under section 1395e(a)(3) of this title).

(4) For purposes of subsection (i), the determination of whether services furnished by or in an institution described in paragraph (1) constitute post-hospital extended care services shall be made in accordance with and subject to such conditions, limitations, and requirements as may be provided in regulations.

(z) Institutional planning

An overall plan and budget of a hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, or home health agency shall be considered sufficient if it—

(1) provides for an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that nothing in this paragraph shall require that there be prepared, in connection with any budget, an item-by-item identification of the components of each type of anticipated expenditure or income);

(2)(A) provides for a capital expenditures plan for at least a 3-year period (including the year to which the operating budget described in paragraph (1) is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure in excess of \$600,000 (or such lesser amount as may be established by the State under section 1320a-1(g)(1) of this title in which the hospital is located) related to the acquisition of land, the improvement of land, buildings, and equipment, and the replacement, modernization, and expansion of the buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(B) provides that such plan is submitted to the agency designated under section 1320a-1(b) of this title, or if no such agency is designated, to the appropriate health planning agency in the State (but this subparagraph shall not apply in the case of a facility exempt from review under section 1320a-1 of this title by reason of section 1320a-1(j) of this title);

(3) provides for review and updating at least annually; and

(4) is prepared, under the direction of the governing body of the institution or agency, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the institution or agency.

(aa) Rural health clinic services and Federally qualified health center services

(1) The term “rural health clinic services” means—

(A) physicians’ services and such services and supplies as are covered under subsection (s)(2)(A) if furnished as an incident to a physician’s professional service and items and services described in subsection (s)(10),

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in

paragraph (5)), by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(1)), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician’s service, and

(C) in the case of a rural health clinic located in an area in which there exists a shortage of home health agencies, part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) furnished by a registered professional nurse or licensed practical nurse to a homebound individual under a written plan of treatment (i) established and periodically reviewed by a physician described in paragraph (2)(B), or (ii) established by a nurse practitioner or physician assistant and periodically reviewed and approved by a physician described in paragraph (2)(B),

when furnished to an individual as an outpatient of a rural health clinic.

(2) The term “rural health clinic” means a facility which—

(A) is primarily engaged in furnishing to outpatients services described in subparagraphs (A) and (B) of paragraph (1);

(B) in the case of a facility which is not a physician-directed clinic, has an arrangement (consistent with the provisions of State and local law relative to the practice, performance, and delivery of health services) with one or more physicians (as defined in subsection (r)(1)) under which provision is made for the periodic review by such physicians of covered services furnished by physician assistants and nurse practitioners, the supervision and guidance by such physicians of physician assistants and nurse practitioners, the preparation by such physicians of such medical orders for care and treatment of clinic patients as may be necessary, and the availability of such physicians for such referral of and consultation for patients as is necessary and for advice and assistance in the management of medical emergencies; and, in the case of a physician-directed clinic, has one or more of its staff physicians perform the activities accomplished through such an arrangement;

(C) maintains clinical records on all patients;

(D) has arrangements with one or more hospitals, having agreements in effect under section 1395cc of this title, for the referral and admission of patients requiring inpatient services or such diagnostic or other specialized services as are not available at the clinic;

(E) has written policies, which are developed with the advice of (and with provision for review of such policies from time to time by) a group of professional personnel, including one or more physicians and one or more physician assistants or nurse practitioners, to govern those services described in paragraph (1) which it furnishes;

(F) has a physician, physician assistant, or nurse practitioner responsible for the execution of policies described in subparagraph (E) and relating to the provision of the clinic’s services;

(G) directly provides routine diagnostic services, including clinical laboratory services, as prescribed in regulations by the Secretary, and has prompt access to additional diagnostic services from facilities meeting requirements under this subchapter;

(H) in compliance with State and Federal law, has available for administering to patients of the clinic at least such drugs and biologicals as are determined by the Secretary to be necessary for the treatment of emergency cases (as defined in regulations) and has appropriate procedures or arrangements for storing, administering, and dispensing any drugs and biologicals;

(I) has a quality assessment and performance improvement program, and appropriate procedures for review of utilization of clinic services, as the Secretary may specify;

(J) has a nurse practitioner, a physician assistant, or a certified nurse-midwife (as defined in subsection (gg)) available to furnish patient care services not less than 50 percent of the time the clinic operates; and

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.

For the purposes of this subchapter, such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 4-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act [42 U.S.C. 254b(b)(3), 300e-1(7)], (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act [42 U.S.C. 254e(a)(1)(A)] because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5)⁸ of that Act, or (IV) as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act [42 U.S.C. 254e(a)(1)(B)], (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under this subchapter, except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1395l of this title, (iii) employs a physician assistant or nurse practitioner, and (iv) is not a rehabilitation agency or a facility which is primarily for the care and treatment of mental diseases. A facility that is in operation and qualifies as a rural health clinic under this subchapter or subchapter XIX and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this subchapter and subchapter XIX, as still sat-

isfying the requirement of such clause if it is determined, in accordance with criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic. If a State agency has determined under section 1395aa(a) of this title that a facility is a rural health clinic and the facility has applied to the Secretary for approval as such a clinic, the Secretary shall notify the facility of the Secretary's approval or disapproval not later than 60 days after the date of the State agency determination or the application (whichever is later).

(3) The term "Federally qualified health center services" means—

(A) services of the type described in subparagraphs (A) through (C) of paragraph (1) and preventive services (as defined in subsection (ddd)(3)); and

(B) preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act [42 U.S.C. 254b],

when furnished to an individual as an outpatient of a Federally qualified health center by the center or by a health care professional under contract with the center and, for this purpose, any reference to a rural health clinic or a physician described in paragraph (2)(B) is deemed a reference to a Federally qualified health center or a physician at the center, respectively.

(4) The term "Federally qualified health center" means an entity which—

(A)(i) is receiving a grant under section 330 of the Public Health Service Act [42 U.S.C. 254b], or

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and (II) meets the requirements to receive a grant under section 330 of such Act [42 U.S.C. 254b];

(B) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant;

(C) was treated by the Secretary, for purposes of part B, as a comprehensive Federally funded health center as of January 1, 1990; or

(D) is an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.] or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(5)(A) The term "physician assistant" and the term "nurse practitioner" mean, for purposes of this subchapter, a physician assistant or nurse practitioner who performs such services as such individual is legally authorized to perform (in the State in which the individual performs such services) in accordance with State law (or the State regulatory mechanism provided by State law), and who meets such training, education, and experience requirements (or any combination thereof) as the Secretary may prescribe in regulations.

(B) The term "clinical nurse specialist" means, for purposes of this subchapter, an individual who—

(i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(ii) holds a master's degree in a defined clinical area of nursing from an accredited educational institution.

(6) The term "collaboration" means a process in which a nurse practitioner works with a physician to deliver health care services within the scope of the practitioner's professional expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as defined by the law of the State in which the services are performed.

(7)(A) The Secretary shall waive for a 1-year period the requirements of paragraph (2) that a rural health clinic employ a physician assistant, nurse practitioner or certified nurse midwife or that such clinic require such providers to furnish services at least 50 percent of the time that the clinic operates for any facility that requests such waiver if the facility demonstrates that the facility has been unable, despite reasonable efforts, to hire a physician assistant, nurse practitioner, or certified nurse-midwife in the previous 90-day period.

(B) The Secretary may not grant such a waiver under subparagraph (A) to a facility if the request for the waiver is made less than 6 months after the date of the expiration of any previous such waiver for the facility, or if the facility has not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic.

(C) A waiver which is requested under this paragraph shall be deemed granted unless such request is denied by the Secretary within 60 days after the date such request is received.

(bb) Services of a certified registered nurse anesthetist

(1) The term "services of a certified registered nurse anesthetist" means anesthesia services and related care furnished by a certified registered nurse anesthetist (as defined in paragraph (2)) which the nurse anesthetist is legally authorized to perform as such by the State in which the services are furnished.

(2) The term "certified registered nurse anesthetist" means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.

(cc) Comprehensive outpatient rehabilitation facility services

(1) The term "comprehensive outpatient rehabilitation facility services" means the following items and services furnished by a physician or other qualified professional personnel (as defined in regulations by the Secretary) to an individual who is an outpatient of a comprehensive

outpatient rehabilitation facility under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician—

(A) physicians' services;

(B) physical therapy, occupational therapy, speech-language pathology services, and respiratory therapy;

(C) prosthetic and orthotic devices, including testing, fitting, or training in the use of prosthetic and orthotic devices;

(D) social and psychological services;

(E) nursing care provided by or under the supervision of a registered professional nurse;

(F) drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered;

(G) supplies and durable medical equipment; and

(H) such other items and services as are medically necessary for the rehabilitation of the patient and are ordinarily furnished by comprehensive outpatient rehabilitation facilities,

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital. In the case of physical therapy, occupational therapy, and speech pathology services, there shall be no requirement that the item or service be furnished at any single fixed location if the item or service is furnished pursuant to such plan and payments are not otherwise made for the item or service under this subchapter.

(2) The term "comprehensive outpatient rehabilitation facility" means a facility which—

(A) is primarily engaged in providing (by or under the supervision of physicians) diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons;

(B) provides at least the following comprehensive outpatient rehabilitation services: (i) physicians' services (rendered by physicians, as defined in subsection (r)(1), who are available at the facility on a full- or part-time basis); (ii) physical therapy; and (iii) social or psychological services;

(C) maintains clinical records on all patients;

(D) has policies established by a group of professional personnel (associated with the facility), including one or more physicians defined in subsection (r)(1) to govern the comprehensive outpatient rehabilitation services it furnishes, and provides for the carrying out of such policies by a full- or part-time physician referred to in subparagraph (B)(i);

(E) has a requirement that every patient must be under the care of a physician;

(F) in the case of a facility in any State in which State or applicable local law provides for the licensing of facilities of this nature (i) is licensed pursuant to such law, or (ii) is approved by the agency of such State or locality, responsible for licensing facilities of this nature, as meeting the standards established for such licensing;

(G) has in effect a utilization review plan in accordance with regulations prescribed by the Secretary;

(H) has in effect an overall plan and budget that meets the requirements of subsection (z);

(I) provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000; and

(J) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities.

The Secretary may waive the requirement of a surety bond under subparagraph (I) in the case of a facility that provides a comparable surety bond under State law.

(dd) Hospice care; hospice program; definitions; certification; waiver by Secretary

(1) The term "hospice care" means the following items and services provided to a terminally ill individual by, or by others under arrangements made by, a hospice program under a written plan (for providing such care to such individual) established and periodically reviewed by the individual's attending physician and by the medical director (and by the interdisciplinary group described in paragraph (2)(B)) of the program—

(A) nursing care provided by or under the supervision of a registered professional nurse,

(B) physical or occupational therapy, or speech-language pathology services,

(C) medical social services under the direction of a physician,

(D)(i) services of a home health aide who has successfully completed a training program approved by the Secretary and (ii) homemaker services,

(E) medical supplies (including drugs and biologicals) and the use of medical appliances, while under such a plan,

(F) physicians' services,

(G) short-term inpatient care (including both respite care and procedures necessary for pain control and acute and chronic symptom management) in an inpatient facility meeting such conditions as the Secretary determines to be appropriate to provide such care, but such respite care may be provided only on an intermittent, nonroutine, and occasional basis and may not be provided consecutively over longer than five days,

(H) counseling (including dietary counseling) with respect to care of the terminally ill individual and adjustment to his death, and

(I) any other item or service which is specified in the plan and for which payment may otherwise be made under this subchapter.

The care and services described in subparagraphs (A) and (D) may be provided on a 24-hour, continuous basis only during periods of crisis (meeting criteria established by the Secretary) and only as necessary to maintain the terminally ill individual at home.

(2) The term "hospice program" means a public agency or private organization (or a subdivision thereof) which—

(A)(i) is primarily engaged in providing the care and services described in paragraph (1)

and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1395d(a)(5) of this title,

(ii) provides for such care and services in individuals' homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that—

(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and

(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1395d(d) of this title with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;

(B) has an interdisciplinary group of personnel which—

(i) includes at least—

(I) one physician (as defined in subsection (r)(1)),

(II) one registered professional nurse, and

(III) one social worker,

employed by or, in the case of a physician described in subclause (I), under contract with the agency or organization, and also includes at least one pastoral or other counselor,

(ii) provides (or supervises the provision of) the care and services described in paragraph (1), and

(iii) establishes the policies governing the provision of such care and services;

(C) maintains central clinical records on all patients;

(D) does not discontinue the hospice care it provides with respect to a patient because of the inability of the patient to pay for such care;

(E)(i) utilizes volunteers in its provision of care and services in accordance with standards set by the Secretary, which standards shall ensure a continuing level of effort to utilize such volunteers, and (ii) maintains records on the use of these volunteers and the cost savings and expansion of care and services achieved through the use of these volunteers;

(F) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, is licensed pursuant to such law; and

(G) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization.

(3)(A) An individual is considered to be “terminally ill” if the individual has a medical prognosis that the individual’s life expectancy is 6 months or less.

(B) The term “attending physician” means, with respect to an individual, the physician (as defined in subsection (r)(1)), the nurse practitioner (as defined in subsection (aa)(5)), or the physician assistant (as defined in such subsection), who may be employed by a hospice program, whom the individual identifies as having the most significant role in the determination and delivery of medical care to the individual at the time the individual makes an election to receive hospice care.

(4)(A) An entity which is certified as a provider of services other than a hospice program shall be considered, for purposes of certification as a hospice program, to have met any requirements under paragraph (2) which are also the same requirements for certification as such other type of provider. The Secretary shall coordinate surveys for determining certification under this subchapter so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

(B) Any entity which is certified as a hospice program and as a provider of another type shall have separate provider agreements under section 1395cc of this title and shall file separate cost reports with respect to costs incurred in providing hospice care and in providing other services and items under this subchapter.

(C) Any entity that is certified as a hospice program shall be subject to a standard survey by an appropriate State or local survey agency, or an approved accreditation agency, as determined by the Secretary, not less frequently than once every 36 months beginning 6 months after October 6, 2014, and ending September 30, 2025.

(5)(A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(I) for an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);

(ii) was in operation on or before January 1, 1983; and

(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

(B) Any waiver, which is in such form and containing such information as the Secretary may require and which is requested by an agency or organization under subparagraph (A) or (C), shall be deemed to be granted unless such request is denied by the Secretary within 60 days after the date such request is received by the Secretary. The granting of a waiver under subparagraph (A) or (C) shall not preclude the

granting of any subsequent waiver request should such a waiver again become necessary.

(C) The Secretary may waive the requirements of paragraph (2)(A)(i) and (2)(A)(ii) for an agency or organization with respect to the services described in paragraph (1)(B) and, with respect to dietary counseling, paragraph (1)(H), if such agency or organization—

(i) is located in an area which is not an urbanized area (as defined by the Bureau of Census), and

(ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program’s service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.

(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive.

(ee) Discharge planning process

(1) A discharge planning process of a hospital shall be considered sufficient if it is applicable to services furnished by the hospital to individuals entitled to benefits under this subchapter and if it meets the guidelines and standards established by the Secretary under paragraph (2).

(2) The Secretary shall develop guidelines and standards for the discharge planning process in order to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

(A) The hospital must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning.

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon the request of the patient, patient’s representative, or patient’s physician.

(C) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(D) A discharge planning evaluation must include an evaluation of a patient’s likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and

entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this subchapter and that serve the area in which the patient resides.

(E) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(F) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(G) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered professional nurse, social worker, or other appropriately qualified personnel.

(H) Consistent with section 1395a of this title, the discharge plan shall—

(i) not specify or otherwise limit the qualified provider which may provide post-hospital home health services, and

(ii) identify (in a form and manner specified by the Secretary) any entity to whom the individual is referred in which the hospital has a disclosable financial interest (as specified by the Secretary consistent with section 1395cc(a)(1)(S) of this title) or which has such an interest in the hospital.

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization—

(A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and

(B) notwithstanding subparagraph (H)(i)⁹, the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

(ff) Partial hospitalization services

(1) The term "partial hospitalization services" means the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

(2) The items and services described in this paragraph are—

(A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),

(B) occupational therapy requiring the skills of a qualified occupational therapist,

(C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,

(D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),

(E) individualized activity therapies that are not primarily recreational or diversionary,

(F) family counseling (the primary purpose of which is treatment of the individual's condition),

(G) patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment),

(H) diagnostic services, and

(I) such other items and services as the Secretary may provide (but in no event to include meals and transportation);

that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

(3)(A) A program described in this paragraph is a program which is furnished by a hospital to its outpatients or by a community mental health center (as defined in subparagraph (B)), and which is a distinct and organized intensive ambulatory treatment service offering less than 24-hour-daily care other than in an individual's home or in an inpatient or residential setting.

(B) For purposes of subparagraph (A), the term "community mental health center" means an entity that—

(i) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act [42 U.S.C. 300x-2(c)(1)]; or

(ii) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);

(i) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located;

(ii) provides at least 40 percent of its services to individuals who are not eligible for benefits under this subchapter; and

(iv) meets such additional conditions as the Secretary shall specify to ensure (I) the health and safety of individuals being furnished such services, (II) the effective and efficient fur-

⁹ So in original. Probably should be "paragraph (2)(H)(i)".

nishing of such services, and (III) the compliance of such entity with the criteria described in section 1931(c)(1) of the Public Health Service Act [42 U.S.C. 300x-31(c)(1)].

(gg) Certified nurse-midwife services

(1) The term “certified nurse-midwife services” means such services furnished by a certified nurse-midwife (as defined in paragraph (2)) and such services and supplies furnished as an incident to the nurse-midwife’s service which the certified nurse-midwife 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 or as an incident to a physicians’ service.

(2) The term “certified nurse-midwife” means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.

(hh) Clinical social worker; clinical social worker services

(1) The term “clinical social worker” means an individual who—

(A) possesses a master’s or doctor’s degree in social work;

(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and

(C)(i) is licensed or certified as a clinical social worker by the State in which the services are performed, or

(ii) in the case of an individual in a State which does not provide for licensure or certification—

(I) 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 (as determined by the Secretary), and

(II) meets such other criteria as the Secretary establishes.

(2) The term “clinical social worker services” means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation) which the clinical social worker 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 as would otherwise be covered if furnished by a physician or as an incident to a physician’s professional service.

(ii) Qualified psychologist services

The term “qualified psychologist services” means such services and such services and supplies furnished as an incident to his service furnished by a clinical psychologist (as defined by the Secretary) which the psychologist 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 or as an incident to a physician’s service.

(jj) Screening mammography

The term “screening mammography” means a radiologic procedure provided to a woman for the purpose of early detection of breast cancer and includes a physician’s interpretation of the results of the procedure.

(kk) Covered osteoporosis drug

The term “covered osteoporosis drug” means an injectable drug approved for the treatment of post-menopausal osteoporosis provided to an individual by a home health agency if, in accordance with regulations promulgated by the Secretary—

(1) the individual’s attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and

(2) the individual is confined to the individual’s home (except when receiving items and services referred to in subsection (m)(7)).

(ll) Speech-language pathology services; audiology services

(1) The term “speech-language pathology services” means such speech, language, and related function assessment and rehabilitation services furnished by a qualified speech-language pathologist as the speech-language pathologist 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.

(2) The term “outpatient speech-language pathology services” has the meaning given the term “outpatient physical therapy services” in subsection (p), except that in applying such subsection—

(A) “speech-language pathology” shall be substituted for “physical therapy” each place it appears; and

(B) “speech-language pathologist” shall be substituted for “physical therapist” each place it appears.

(3) The term “audiology services” 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.

(4) In this subsection:

(A) The term “qualified speech-language pathologist” means an individual with a master’s or doctoral degree in speech-language pathology who—

(i) is licensed as a speech-language pathologist by the State in which the individual furnishes such services, or

(ii) in the case of an individual who furnishes services in a State which does not license speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months

of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

(B) The term "qualified audiologist" means an individual with a master's or doctoral degree in audiology who—

(i) is licensed as an audiologist by the State in which the individual furnishes such services, or

(ii) 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), 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.

(mm) Critical access hospital; critical access hospital services

(1) The term "critical access hospital" means a facility certified by the Secretary as a critical access hospital under section 1395l-4(e) of this title.

(2) The term "inpatient critical access hospital services" means items and services, furnished to an inpatient of a critical access hospital by such facility, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

(3) The term "outpatient critical access hospital services" means medical and other health services furnished by a critical access hospital on an outpatient basis.

(nn) Screening pap smear; screening pelvic exam

(1) The term "screening pap smear" means a diagnostic laboratory test consisting of a routine exfoliative cytology test (Papanicolaou test) provided to a woman for the purpose of early detection of cervical or vaginal cancer and includes a physician's interpretation of the results of the test, if the individual involved has not had such a test during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3).

(2) The term "screening pelvic exam" means a pelvic examination provided to a woman if the woman involved has not had such an examination during the preceding 2 years, or during the preceding year in the case of a woman described in paragraph (3), and includes a clinical breast examination.

(3) A woman described in this paragraph is a woman who—

(A) is of childbearing age and has had a test described in this subsection during any of the preceding 3 years that indicated the presence of cervical or vaginal cancer or other abnormality; or

(B) is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).

(oo) Prostate cancer screening tests

(1) The term "prostate cancer screening test" means a test that consists of any (or all) of the procedures described in paragraph (2) provided for the purpose of early detection of prostate cancer to a man over 50 years of age who has not had such a test during the preceding year.

(2) The procedures described in this paragraph are as follows:

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

(C) For years beginning after 2002, such other procedures as the Secretary finds appropriate for the purpose of early detection of prostate cancer, taking into account changes in technology and standards of medical practice, availability, effectiveness, costs, and such other factors as the Secretary considers appropriate.

(pp) Colorectal cancer screening tests

(1) The term "colorectal cancer screening test" means any of the following procedures furnished to an individual for the purpose of early detection of colorectal cancer:

(A) Screening fecal-occult blood test.

(B) Screening flexible sigmoidoscopy.

(C) Screening colonoscopy.

(D) Such other tests or procedures, and modifications to tests and procedures under this subsection, with such frequency and payment limits, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) An "individual at high risk for colorectal cancer" is an individual who, because of family history, prior experience of cancer or precursor neoplastic polyps, a history of chronic digestive disease condition (including inflammatory bowel disease, Crohn's Disease, or ulcerative colitis), the presence of any appropriate recognized gene markers for colorectal cancer, or other predisposing factors, faces a high risk for colorectal cancer.

(qq) Diabetes outpatient self-management training services

(1) The term "diabetes outpatient self-management training services" means educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B), but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

(2) In paragraph (1)—

(A) a "certified provider" is a physician, or other individual or entity designated by the Secretary, that, in addition to providing diabetes outpatient self-management training services, provides other items or services for

which payment may be made under this subchapter; and

(B) a physician, or such other individual or entity, meets the quality standards described in this paragraph if the physician, or individual or entity, meets quality standards established by the Secretary, except that the physician or other individual or entity shall be deemed to have met such standards if the physician or other individual or entity meets applicable standards originally established by the National Diabetes Advisory Board and subsequently revised by organizations who participated in the establishment of standards by such Board, or is recognized by an organization that represents individuals (including individuals under this subchapter) with diabetes as meeting standards for furnishing the services.

(rr) Bone mass measurement

(1) The term “bone mass measurement” means a radiologic or radioisotopic procedure or other procedure approved by the Food and Drug Administration performed on a qualified individual (as defined in paragraph (2)) for the purpose of identifying bone mass or detecting bone loss or determining bone quality, and includes a physician’s interpretation of the results of the procedure.

(2) For purposes of this subsection, the term “qualified individual” means an individual who is (in accordance with regulations prescribed by the Secretary)—

(A) an estrogen-deficient woman at clinical risk for osteoporosis;

(B) an individual with vertebral abnormalities;

(C) an individual receiving long-term glucocorticoid steroid therapy;

(D) an individual with primary hyperparathyroidism; or

(E) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy.

(3) The Secretary shall establish such standards regarding the frequency with which a qualified individual shall be eligible to be provided benefits for bone mass measurement under this subchapter.

(ss) Religious nonmedical health care institution

(1) The term “religious nonmedical health care institution” means an institution that—

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of such section;

(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;

(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;

(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;

(E) provides such nonmedical items and services to inpatients on a 24-hour basis;

(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

(G)(i) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;

(ii) is not affiliated with—

(I) a provider of medical treatment or services, or

(II) an individual who has an ownership interest in a provider of medical treatment or services;

(H) has in effect a utilization review plan which—

(i) provides for the review of admissions to the institution, of the duration of stays therein, of cases of continuous extended duration, and of the items and services furnished by the institution,

(ii) requires that such reviews be made by an appropriate committee of the institution that includes the individuals responsible for overall administration and for supervision of nursing personnel at the institution,

(iii) provides that records be maintained of the meetings, decisions, and actions of such committee, and

(iv) meets such other requirements as the Secretary finds necessary to establish an effective utilization review plan;

(I) provides the Secretary with such information as the Secretary may require to implement section 1395i-5 of this title, including information relating to quality of care and coverage determinations; and

(J) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

(2) To the extent that the Secretary finds that the accreditation of an institution by a State, regional, or national agency or association provides reasonable assurances that any or all of the requirements of paragraph (1) are met or exceeded, the Secretary may treat such institution as meeting the condition or conditions with respect to which the Secretary made such finding.

(3)(A)(i) In administering this subsection and section 1395i-5 of this title, the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects thereto on religious grounds.

(ii) Clause (i) shall not be construed as preventing the Secretary from requiring under section 1395i-5(a)(2) of this title the provision of sufficient information regarding an individual’s condition as a condition for receipt of benefits under part A for services provided in such an institution.

(B)(i) In administering this subsection and section 1395i-5 of this title, the Secretary shall not subject a religious nonmedical health care insti-

tution or its personnel to any medical supervision, regulation, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or such personnel.

(ii) Clause (i) shall not be construed as preventing the Secretary from reviewing items and services billed by the institution to the extent the Secretary determines such review to be necessary to determine whether such items and services were not covered under part A, are excessive, or are fraudulent.

(4)(A) For purposes of paragraph (1)(G)(i), an ownership interest of less than 5 percent shall not be taken into account.

(B) For purposes of paragraph (1)(G)(ii), none of the following shall be considered to create an affiliation:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of a religious non-medical health care institution.

(ii) An individual who is a director, trustee, officer, employee, or staff member of a religious nonmedical health care institution having a family relationship with an individual who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) An individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and religious nonmedical health care institutions.

(tt) Post-institutional home health services; home health spell of illness

(1) The term “post-institutional home health services” means home health services furnished to an individual—

(A) after discharge from a hospital or critical access hospital in which the individual was an inpatient for not less than 3 consecutive days before such discharge if such home health services were initiated within 14 days after the date of such discharge; or

(B) after discharge from a skilled nursing facility in which the individual was provided post-hospital extended care services if such home health services were initiated within 14 days after the date of such discharge.

(2) The term “home health spell of illness” with respect to any individual means a period of consecutive days—

(A) beginning with the first day (not included in a previous home health spell of illness) (i) on which such individual is furnished post-institutional home health services, and (ii) which occurs in a month for which the individual is entitled to benefits under part A, and

(B) ending with the close of the first period of 60 consecutive days thereafter on each of which the individual is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1395i-3(a)(1) of this title or subsection (y)(1) nor provided home health services.

(uu) Screening for glaucoma

The term “screening for glaucoma” means a dilated eye examination with an intraocular

pressure measurement, and a direct ophthalmoscopy or a slit-lamp biomicroscopic examination for the early detection of glaucoma which is furnished by or under the direct supervision of an optometrist or ophthalmologist who is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished, as would otherwise be covered if furnished by a physician or as an incident to a physician’s professional service, if the individual involved has not had such an examination in the preceding year.

(vv) Medical nutrition therapy services; registered dietitian or nutrition professional

(1) The term “medical nutrition therapy services” means nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional (as defined in paragraph (2)) pursuant to a referral by a physician (as defined in subsection (r)(1)).

(2) Subject to paragraph (3), the term “registered dietitian or nutrition professional” means an individual who—

(A) holds a baccalaureate or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized by the Secretary for this purpose;

(B) has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional; and

(C)(i) is licensed or certified as a dietitian or nutrition professional by the State in which the services are performed; or

(ii) in the case of an individual in a State that does not provide for such licensure or certification, meets such other criteria as the Secretary establishes.

(3) Subparagraphs (A) and (B) of paragraph (2) shall not apply in the case of an individual who, as of December 21, 2000, is licensed or certified as a dietitian or nutrition professional by the State in which medical nutrition therapy services are performed.

(ww) Initial preventive physical examination

(1) The term “initial preventive physical examination” means physicians’ services consisting of a physical examination (including measurement of height, weight body mass index,¹⁰ and blood pressure) with the goal of health promotion and disease detection and includes education, counseling, and referral with respect to screening and other preventive services described in paragraph (2), end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, and the furnishing of a review of any current opioid prescriptions (as defined in paragraph (4)), but does not include clinical laboratory tests.

(2) The screening and other preventive services described in this paragraph include the following:

¹⁰So in original. Probably should be “weight, body mass index.”

(A) Pneumococcal, influenza, and hepatitis B vaccine and administration under subsection (s)(10).

(B) Screening mammography as defined in subsection (jj).

(C) Screening pap smear and screening pelvic exam as defined in subsection (nn).

(D) Prostate cancer screening tests as defined in subsection (oo).

(E) Colorectal cancer screening tests as defined in subsection (pp).

(F) Diabetes outpatient self-management training services as defined in subsection (qq)(1).

(G) Bone mass measurement as defined in subsection (rr).

(H) Screening for glaucoma as defined in subsection (uu).

(I) Medical nutrition therapy services as defined in subsection (vv).

(J) Cardiovascular screening blood tests as defined in subsection (xx)(1).

(K) Diabetes screening tests as defined in subsection (yy).

(L) Ultrasound screening for abdominal aortic aneurysm as defined in subsection (bbb).

(M) An electrocardiogram.

(N) Screening for potential substance use disorders.

(O) Additional preventive services (as defined in subsection (ddd)(1)).

(3) For purposes of paragraph (1), the term “end-of-life planning” means verbal or written information regarding—

(A) an individual’s ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and

(B) whether or not the physician is willing to follow the individual’s wishes as expressed in an advance directive.

(4) For purposes of paragraph (1), the term “a review of any current opioid prescriptions” means, with respect to an individual determined to have a current prescription for opioids—

(A) a review of the potential risk factors to the individual for opioid use disorder;

(B) an evaluation of the individual’s severity of pain and current treatment plan;

(C) the provision of information on non-opioid treatment options; and

(D) a referral to a specialist, as appropriate.

(xx) Cardiovascular screening blood test

(1) The term “cardiovascular screening blood test” means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) Cholesterol levels and other lipid or triglyceride levels.

(B) Such other indications associated with the presence of, or an elevated risk for, cardiovascular disease as the Secretary may approve for all individuals (or for some individuals determined by the Secretary to be at risk for cardiovascular disease), including indications measured by noninvasive testing.

The Secretary may not approve an indication under subparagraph (B) for any individual unless

a blood test for such is recommended by the United States Preventive Services Task Force.

(2) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency for each type of cardiovascular screening blood tests, except that such frequency may not be more often than once every 2 years.

(yy) Diabetes screening tests

(1) The term “diabetes screening tests” means testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including—

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

(2) For purposes of paragraph (1), the term “individual at risk for diabetes” means an individual who has any of the following risk factors for diabetes:

(A) Hypertension.

(B) Dyslipidemia.

(C) Obesity, defined as a body mass index greater than or equal to 30 kg/m².

(D) Previous identification of an elevated impaired fasting glucose.

(E) Previous identification of impaired glucose tolerance.

(F) A risk factor consisting of at least 2 of the following characteristics:

(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m².

(ii) A family history of diabetes.

(iii) A history of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

(iv) 65 years of age or older.

(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

(zz) Intravenous immune globulin

The term “intravenous immune globulin” means an approved pooled plasma derivative for the treatment in the patient’s home of a patient with a diagnosed primary immune deficiency disease, but not including items or services related to the administration of the derivative, if a physician determines administration of the derivative in the patient’s home is medically appropriate.

(aaa) Extended care in religious nonmedical health care institutions

(1) The term “home health agency” also includes a religious nonmedical health care institution (as defined in subsection (ss)(1)), but only with respect to items and services ordinarily furnished by such an institution to individuals in their homes, and that are comparable to items and services furnished to individuals by a home health agency that is not religious non-medical health care institution.

(2)(A) Subject to subparagraphs (B), payment may be made with respect to services provided by such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations consistent with section 1395i-5 of this title.

(B) Notwithstanding any other provision of this subchapter, payment may not be made under subparagraph (A)—

- (i) in a year insofar as such payments exceed \$700,000; and
- (ii) after December 31, 2006.

(bbb) Ultrasound screening for abdominal aortic aneurysm

The term “ultrasound screening for abdominal aortic aneurysm” means—

(1) a procedure using sound waves (or such other procedures using alternative technologies, of commensurate accuracy and cost, that the Secretary may specify) provided for the early detection of abdominal aortic aneurysm; and

(2) includes a physician’s interpretation of the results of the procedure.

(ccc) Long-term care hospital

The term “long-term care hospital” means a hospital which—

(1) is primarily engaged in providing inpatient services, by or under the supervision of a physician, to Medicare beneficiaries whose medically complex conditions require a long hospital stay and programs of care provided by a long-term care hospital;

(2) has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or meets the requirements of clause (II)⁸ of section 1395ww(d)(1)(B)(iv) of this title;

(3) satisfies the requirements of subsection (e); and

(4) meets the following facility criteria:

(A) the institution has a patient review process, documented in the patient medical record, that screens patients prior to admission for appropriateness of admission to a long-term care hospital, validates within 48 hours of admission that patients meet admission criteria for long-term care hospitals, regularly evaluates patients throughout their stay for continuation of care in a long-term care hospital, and assesses the available discharge options when patients no longer meet such continued stay criteria;

(B) the institution has active physician involvement with patients during their treatment through an organized medical staff, physician-directed treatment with physician on-site availability on a daily basis to review patient progress, and consulting physicians on call and capable of being at the patient’s side within a moderate period of time, as determined by the Secretary; and

(C) the institution has interdisciplinary team treatment for patients, requiring interdisciplinary teams of health care professionals, including physicians, to prepare and carry out an individualized treatment plan for each patient.

(ddd) Additional preventive services; preventive services

(1) The term “additional preventive services” means services not described in subparagraph (A) or (C) of paragraph (3) that identify medical conditions or risk factors and that the Secretary determines are—

(A) reasonable and necessary for the prevention or early detection of an illness or disability;

(B) recommended with a grade of A or B by the United States Preventive Services Task Force; and

(C) appropriate for individuals entitled to benefits under part A or enrolled under part B.

(2) In making determinations under paragraph (1) regarding the coverage of a new service, the Secretary shall use the process for making national coverage determinations (as defined in section 1395ff(f)(1)(B) of this title) under this subchapter. As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such service and may take into account the results of such assessment in making such determination.

(3) The term “preventive services” means the following:

(A) The screening and preventive services described in subsection (ww)(2) (other than the service described in subparagraph (M) of such subsection).

(B) An initial preventive physical examination (as defined in subsection (ww)).

(C) Personalized prevention plan services (as defined in subsection (hhh)(1)).

(eee) Cardiac rehabilitation program; intensive cardiac rehabilitation program

(1) The term “cardiac rehabilitation program” means a physician-supervised program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3).

(2) A program described in this paragraph is a program under which—

(A) items and services under the program are delivered—

(i) in a physician’s office;

(ii) in a hospital on an outpatient basis; or

(iii) in other settings determined appropriate by the Secretary.

(B) a physician is immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed; and

(C) individualized treatment is furnished under a written plan established, reviewed, and signed by a physician every 30 days that describes—

(i) the individual’s diagnosis;

(ii) the type, amount, frequency, and duration of the items and services furnished under the plan; and

(iii) the goals set for the individual under the plan.

(3) The items and services described in this paragraph are—

(A) physician-prescribed exercise;
 (B) cardiac risk factor modification, including education, counseling, and behavioral intervention (to the extent such education, counseling, and behavioral intervention is closely related to the individual's care and treatment and is tailored to the individual's needs);

(C) psychosocial assessment;
 (D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(4)(A) The term "intensive cardiac rehabilitation program" means a physician-supervised program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) and has shown, in peer-reviewed published research, that it accomplished—

(i) one or more of the following:

(I) positively affected the progression of coronary heart disease; or

(II) reduced the need for coronary bypass surgery; or

(III) reduced the need for percutaneous coronary interventions; and

(ii) a statistically significant reduction in 5 or more of the following measures from their level before receipt of cardiac rehabilitation services to their level after receipt of such services:

(I) low density lipoprotein;

(II) triglycerides;

(III) body mass index;

(IV) systolic blood pressure;

(V) diastolic blood pressure; or

(VI) the need for cholesterol, blood pressure, and diabetes medications.

(B) To be eligible for an intensive cardiac rehabilitation program, an individual must have—

(i) had an acute myocardial infarction within the preceding 12 months;

(ii) had coronary bypass surgery;

(iii) stable angina pectoris;

(iv) had heart valve repair or replacement;

(v) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;

(vi) had a heart or heart-lung transplant;

(vii) stable, chronic heart failure (defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks); or

(viii) any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process

used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.

(C) An intensive cardiac rehabilitation program may be provided in a series of 72 one-hour sessions (as defined in section 1395w-4(b)(5) of this title), up to 6 sessions per day, over a period of up to 18 weeks.

(5) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology who is licensed to practice medicine in the State in which a cardiac rehabilitation program (or the intensive cardiac rehabilitation program, as the case may be) is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual¹ in the program.

(fff) Pulmonary rehabilitation program

(1) The term "pulmonary rehabilitation program" means a physician-supervised program (as described in subsection (eee)(2) with respect to a program under this subsection) that furnishes the items and services described in paragraph (2).

(2) The items and services described in this paragraph are—

(A) physician-prescribed exercise;

(B) education or training (to the extent the education or training is closely and clearly related to the individual's care and treatment and is tailored to such individual's needs);

(C) psychosocial assessment;

(D) outcomes assessment; and

(E) such other items and services as the Secretary may determine, but only if such items and services are—

(i) reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(ii) reasonably expected to improve or maintain the individual's condition and functional level; and

(iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(3) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with respiratory pathophysiology who is licensed to practice medicine in the State in which a pulmonary rehabilitation program is offered—

(A) is responsible for such program; and

(B) in consultation with appropriate staff, is involved substantially in directing the progress of individual¹ in the program.

(ggg) Kidney disease education services

(1) The term "kidney disease education services" means educational services that are—

(A) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;

(B) furnished, upon the referral of the physician managing the individual's kidney condition, by a qualified person (as defined in paragraph (2)); and

(C) designed—

(i) to provide comprehensive information (consistent with the standards set under paragraph (3)) regarding—

(I) the management of comorbidities, including for purposes of delaying the need for dialysis;

(II) the prevention of uremic complications; and

(III) each option for renal replacement therapy (including hemodialysis and peritoneal dialysis at home and in-center as well as vascular access options and transplantation);

(ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy; and

(iii) to be tailored to meet the needs of the individual involved.

(2)(A) The term “qualified person” means—

(i) a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in subsection (aa)(5)), who furnishes services for which payment may be made under the fee schedule established under section 1395w-4 of this title; and

(ii) a provider of services located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(ii)) or a renal dialysis facility.

(3) The Secretary shall set standards for the content of such information to be provided under paragraph (1)(C)(i) after consulting with physicians, other health professionals, health educators, professional organizations, accrediting organizations, kidney patient organizations, dialysis facilities, transplant centers, network organizations described in section 1395rr(c)(2) of this title, and other knowledgeable persons. To the extent possible the Secretary shall consult with persons or entities described in the previous sentence, other than a dialysis facility, that has not received industry funding from a drug or biological manufacturer or dialysis facility.

(4) No individual shall be furnished more than 6 sessions of kidney disease education services under this subchapter.

(hhh) Annual wellness visit

(1) The term “personalized prevention plan services” means the creation of a plan for an individual—

(A) that includes a health risk assessment (that meets the guidelines established by the Secretary under paragraph (4)(A)) of the individual that is completed prior to or as part of the same visit with a health professional described in paragraph (3); and

(B) that—

(i) takes into account the results of the health risk assessment; and

(ii) may contain the elements described in paragraph (2).

(2) Subject to paragraph (4)(H), the elements described in this paragraph are the following:

(A) The establishment of, or an update to, the individual's medical and family history.

(B) A list of current providers and suppliers that are regularly involved in providing medical care to the individual (including a list of all prescribed medications).

(C) A measurement of height, weight, body mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements.

(D) Detection of any cognitive impairment.

(E) The establishment of, or an update to, the following:

(i) A screening schedule for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices, and the individual's health status, screening history, and age-appropriate preventive services covered under this subchapter.

(ii) A list of risk factors and conditions for which primary, secondary, or tertiary prevention interventions are recommended or are underway, including any mental health conditions or any such risk factors or conditions that have been identified through an initial preventive physical examination (as described under subsection (ww)(1)), and a list of treatment options and their associated risks and benefits.

(F) The furnishing of personalized health advice 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.

(G) Screening for potential substance use disorders and referral for treatment as appropriate.

(H) The furnishing of a review of any current opioid prescriptions (as defined in subsection (ww)(4)).

(I) Any other element determined appropriate by the Secretary.

(3) A health professional described in this paragraph is—

(A) a physician;

(B) a practitioner described in clause (i) of section 1395u(b)(18)(C) of this title; or

(C) a medical professional (including a health educator, registered dietitian, or nutrition professional) or a team of medical professionals, as determined appropriate by the Secretary, under the supervision of a physician.

(4)(A) For purposes of paragraph (1)(A), the Secretary, not later than 1 year after March 23, 2010, shall establish publicly available guidelines for health risk assessments. Such guidelines shall be developed in consultation with relevant groups and entities and shall provide that a health risk assessment—

(i) identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of the individual; and

(ii) may be furnished—

(I) through an interactive telephonic or web-based program that meets the standards established under subparagraph (B);

(II) during an encounter with a health care professional;

(III) through community-based prevention programs; or

(IV) through any other means the Secretary determines appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of such beneficiaries.

(B) Not later than 1 year after March 23, 2010, the Secretary shall establish standards for interactive telephonic or web-based programs used to furnish health risk assessments under subparagraph (A)(ii)(I). The Secretary may utilize any health risk assessment developed under section 300u-12(f) of this title as part of the requirement to develop a personalized prevention plan to comply with this subparagraph.

(C)(i) Not later than 18 months after March 23, 2010, the Secretary shall develop and make available to the public a health risk assessment model. Such model shall meet the guidelines under subparagraph (A) and may be used to meet the requirement under paragraph (1)(A).

(ii) Any health risk assessment that meets the guidelines under subparagraph (A) and is approved by the Secretary may be used to meet the requirement under paragraph (1)(A).

(D) The Secretary may coordinate with community-based entities (including State Health Insurance Programs, Area Agencies on Aging, Aging and Disability Resource Centers, and the Administration on Aging) to—

(i) ensure that health risk assessments are accessible to beneficiaries; and

(ii) provide appropriate support for the completion of health risk assessments by beneficiaries.

(E) The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment prior to or at the same time as receiving personalized prevention plan services.

(F) To the extent practicable, the Secretary shall encourage the use of, integration with, and coordination of health information technology (including use of technology that is compatible with electronic medical records and personal health records) and may experiment with the use of personalized technology to aid in the development of self-management skills and management of and adherence to provider recommendations in order to improve the health status of beneficiaries.

(G) A beneficiary shall be eligible to receive only an initial preventive physical examination (as defined under subsection (ww)(1)) during the 12-month period after the date that the beneficiary's coverage begins under part B and shall be eligible to receive personalized prevention plan services under this subsection each year thereafter provided that the beneficiary has not

received either an initial preventive physical examination or personalized prevention plan services within the preceding 12-month period.

(H) The Secretary shall issue guidance that—

(i) identifies elements under paragraph (2) that are required to be provided to a beneficiary as part of their first visit for personalized prevention plan services; and

(ii) establishes a yearly schedule for appropriate provision of such elements thereafter.

(iii) Home infusion therapy

(1) The term “home infusion therapy” means the items and services described in paragraph (2) furnished by a qualified home infusion therapy supplier (as defined in paragraph (3)(D)) which are furnished in the individual's home (as defined in paragraph (3)(B)) to an individual—

(A) who is under the care of an applicable provider (as defined in paragraph (3)(A)); and

(B) with respect to whom a plan prescribing the type, amount, and duration of infusion therapy services that are to be furnished such individual has been established by a physician (as defined in subsection (r)(1)) and is periodically reviewed by a physician (as so defined) in coordination with the furnishing of home infusion drugs (as defined in paragraph (3)(C)) under part B.

(2) The items and services described in this paragraph are the following:

(A) Professional services, including nursing services, furnished in accordance with the plan.

(B) Training and education (not otherwise paid for as durable medical equipment (as defined in subsection (n)), remote monitoring, and monitoring services for the provision of home infusion therapy and home infusion drugs furnished by a qualified home infusion therapy supplier.

(3) For purposes of this subsection:

(A) The term “applicable provider” means—

(i) a physician;

(ii) a nurse practitioner; and

(iii) a physician assistant.

(B) The term “home” means a place of residence used as the home of an individual (as defined for purposes of subsection (n)).

(C) The term “home infusion drug” means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment (as defined in subsection (n)). Such term does not include the following:

(i) Insulin pump systems.

(ii) A self-administered drug or biological on a self-administered drug exclusion list.

(D)(i) The term “qualified home infusion therapy supplier” means a pharmacy, physician, or other provider of services or supplier licensed by the State in which the pharmacy, physician, or provider or services or supplier furnishes items or services and that—

(I) furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs;

(II) ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis;

(III) is accredited by an organization designated by the Secretary pursuant to section 1395m(u)(5) of this title; and

(IV) meets such other requirements as the Secretary determines appropriate, taking into account the standards of care for home infusion therapy established by Medicare Advantage plans under part C and in the private sector.

(ii) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider of services, or supplier to meet the requirements of this subparagraph.

(jjj) Opioid use disorder treatment services; opioid treatment program

(1) Opioid use disorder treatment services

The term “opioid use disorder treatment services” means items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder, including—

(A) opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 355 of title 21 for use in the treatment of opioid use disorder;

(B) dispensing and administration of such medications, if applicable;

(C) substance use counseling by a professional to the extent authorized under State law to furnish such services;

(D) individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law);

(E) toxicology testing, and

(F) other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

(2) Opioid treatment program

The term “opioid treatment program” means an entity that is an opioid treatment program (as defined in section 8.2 of title 42 of the Code of Federal Regulations, or any successor regulation) that—

(A) is enrolled under section 1395cc(j) of this title;

(B) has in effect a certification by the Substance Abuse and Mental Health Services Administration for such a program;

(C) is accredited by an accrediting body approved by the Substance Abuse and Mental Health Services Administration; and

(D) meets such additional conditions as the Secretary may find necessary to ensure—

(i) the health and safety of individuals being furnished services under such program; and

(ii) the effective and efficient furnishing of such services.

(Aug. 14, 1935, ch. 531, title XVIII, § 1861, as added Pub. L. 89-97, title I, § 102(a), July 30, 1965, 79 Stat. 313; amended Pub. L. 89-713, § 7, Nov. 2, 1966, 80 Stat. 1111; Pub. L. 90-248, title I, §§ 127(a), 129(a), (b), (c)(9)(C), (10), (11), 132(a), 133(a), (b), 134(a), 143(a), 144(a)-(d), Jan. 2, 1968, 81 Stat.

846-850, 852, 857, 858; Pub. L. 91-690, Jan. 12, 1971, 84 Stat. 2074; Pub. L. 92-603, title II, §§ 211(b), (c)(2), 221(c)(4), 223(a)-(d), (f), 227(a), (c), (d)(1), (f), 234(a)-(f), 237(c), 244(c), 246(b), 248, 249(b), 251(a)(1), (b)(1), (c), 252(a), 256(b), 264(a), 265, 267, 273(a), 276(a), 278(a) (4)-(15), (b)(6), (10), (11), (13), 283(a), Oct. 30, 1972, 86 Stat. 1383, 1384, 1389, 1393, 1394, 1404-1407, 1412, 1413, 1416, 1423-1426, 1445-1447, 1449-1454, 1456; Pub. L. 94-182, title I, §§ 102, 106(a), 112(a)(1), Dec. 31, 1975, 89 Stat. 1051, 1052, 1055; Pub. L. 95-142, §§ 3(a)(2), 5(m), 19(b)(1), 21(a), Oct. 25, 1977, 91 Stat. 1178, 1191, 1204, 1207; Pub. L. 95-210, § 1(d), (g), (h), Dec. 13, 1977, 91 Stat. 1485, 1487, 1488; Pub. L. 95-216, title V, § 501(a), Dec. 20, 1977, 91 Stat. 1564; Pub. L. 95-292, § 4(d), June 13, 1978, 92 Stat. 315; Pub. L. 96-499, title IX, §§ 902(a)(1), 915(a), 930(k)-(n), (p), 931(c), (d), 933(c)-(e), 936(a), 937(a), 938(a), 948(a)(1), 949, 950, 951(a), (b), 952(a), formerly 952, Dec. 5, 1980, 94 Stat. 2612, 2623, 2632, 2633, 2635, 2639, 2640, 2643, 2645, 2646; Pub. L. 96-611, § 1(a)(1), (b)(3), Dec. 28, 1980, 94 Stat. 3566; Pub. L. 97-35, title XXI, §§ 2102(a), 2114, 2121(c), (d), 2141(a), 2142(a), 2143(a), 2144(a), 2193(c)(9), Aug. 13, 1981, 95 Stat. 787, 796-799, 828; Pub. L. 97-248, title I, §§ 101(a)(2), (d), 102(a), 103(a), 105(a), 106(a), 107(a), 108(a)(2), 109(b), 114(b), 122(d), 127(1), 128(a)(1), (d)(2), 148(b), Sept. 3, 1982, 96 Stat. 335-339, 350, 359, 366, 367, 394; Pub. L. 97-448, title III, § 309(a)(4), Jan. 12, 1983, 96 Stat. 2408; Pub. L. 98-21, title VI, §§ 602(d), 607(b)(2), (d), Apr. 20, 1983, 97 Stat. 163, 171, 172; Pub. L. 98-369, div. B, title III, §§ 2314(a), 2318(a), (b), 2319(a), 2321(e), 2322(a), 2323(a), 2324(a), 2335(b), 2340(a), 2341(a), (c), 2342(a), 2343(a), (b), 2354(b)(18)-(29), July 18, 1984, 98 Stat. 1079, 1081, 1082, 1085, 1086, 1090, 1093, 1094, 1101; Pub. L. 98-617, § 3(a)(4), (b)(7), Nov. 8, 1984, 98 Stat. 3295, 3296; Pub. L. 99-272, title IX, §§ 9107(b), 9110(a), 9202(i)(1), 9219(b)(1)(B), (3)(A), Apr. 7, 1986, 100 Stat. 160, 162, 177, 182, 183; Pub. L. 99-509, title IX, §§ 9305(c)(1), (2), 9313(a)(2), 9315(a), 9320(b), (c), (f), 9335(c)(1), 9336(a), 9337(d), 9338(a), Oct. 21, 1986, 100 Stat. 1989, 2002, 2005, 2013, 2015, 2030, 2033, 2034; Pub. L. 100-203, title IV, §§ 4009(e)(1), (f), 4021(a), 4026(a)(1), 4039(b), 4064(e)(1), 4065(a), 4070(b)(1), (2), 4071(a), 4072(a), 4073(a), (c), 4074(a), (b), 4075(a), 4076(a), 4077(a)(1), (b)(1), (4), formerly (5), 4078, 4084(c)(1), 4085(i)(9)-(14), 4201(a)(1), (b)(1), (d)(1), (2), (5), formerly (d), Dec. 22, 1987, 101 Stat. 1330-57, 1330-58, 1330-67, 1330-74, 1330-81, 1330-111, 1330-112, 1330-114, 1330-116, 1330-118 to 1330-121, 1330-132, 1330-133, 1330-160, 1330-174, as amended Pub. L. 100-360, title IV, § 411(h)(4)(D), (5)-(7)(A), (E), (F), (i)(3), (4)(C)(iii), (J)(1)(B), (C), July 1, 1988, 102 Stat. 787-789, 801, as amended Pub. L. 100-485, title VI, § 608(d)(27)(B), Oct. 13, 1988, 102 Stat. 2422; Pub. L. 100-360, title I, § 104(d)(4), title II, §§ 202(a), 203(b), (e)(1), 204(a), 205(b), 206(a), title IV, § 411(d)(1)(B)(i), (5)(A), (g)(3)(H), (h)(1)(B), (2), (3)(A), July 1, 1988, 102 Stat. 689, 702, 721, 725, 730, 731, 773, 774, 785, 786; Pub. L. 100-485, title VI, § 608(d)(6)(A), (23)(B), Oct. 13, 1988, 102 Stat. 2414, 2421; Pub. L. 100-647, title VIII, §§ 8423(a), 8424(a), Nov. 10, 1988, 102 Stat. 3803; Pub. L. 101-234, title I, § 101(a), title II, § 201(a), Dec. 13, 1989, 103 Stat. 1979, 1981; Pub. L. 101-239, title VI, §§ 6003(g)(3)(A), (C)(i), (D)(x), 6110, 6112(e)(1), 6113(a)-(b)(2), 6114(a), (d), 6115(a), 6116(a)(1), 6131(a)(2), 6141(a), 6213(a)-(c), Dec. 19, 1989, 103 Stat. 2151-2153, 2213, 2215-2219, 2221, 2225, 2250, 2251; Pub. L. 101-508, title IV,

§§ 4008(h)(2)(A)(i), 4151(a), (b)(1), 4152(a)(2), 4153(b)(2)(A), 4155(a), (d), 4156(a), 4157(a), 4161(a)(1), (2), (5), (b)(1), (2), 4162(a), 4163(a), 4201(d)(1), 4207(d)(1), formerly 4027(d)(1), Nov. 5, 1990, 104 Stat. 1388–48, 1388–71, 1388–72, 1388–74, 1388–84, 1388–86 to 1388–88, 1388–93 to 1388–96, 1388–104, 1388–120, renumbered Pub. L. 103–432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444; Pub. L. 101–597, title IV, §401(c)(2), Nov. 16, 1990, 104 Stat. 3035; Pub. L. 103–66, title XIII, §§13503(c)(1)(A), 13521, 13522, 13553(a), (b), 13554(a), 13556(a), 13564(a)(2), (b)(1), 13565, 13566(b), Aug. 10, 1993, 107 Stat. 578, 586, 591, 592, 607; Pub. L. 103–432, title I, §§102(g)(4), 104, 107(a), 145(b), 146(a), (b), 147(e)(1), (4), (5), (f)(3), (4)(A), (6)(A), (B), (E), 158(a)(1), Oct. 31, 1994, 108 Stat. 4404, 4405, 4407, 4427–4432, 4442; Pub. L. 104–299, §4(b)(1), Oct. 11, 1996, 110 Stat. 3645; Pub. L. 105–33, title IV, §§4102(a), (c), 4103(a), 4104(a)(1), 4105(a)(1), (b)(1), 4106(a), 4201(c)(1), (2), 4205(b)(1), (c)(1), (d)(1)–(3)(A), 4312(b)(1), (2), (d), (e), 4320, 4321(a), 4404(a), 4432(b)(5)(D), (E), 4444(a), 4445, 4446, 4451, 4454(a)(1), 4511(a)(1)–(2)(B), (d), 4512(a), 4513(a), 4522, 4531(a)(1), 4557(a), 4601(a), 4602(a)–(c), 4604(b), 4611(b), 4612(a), Aug. 5, 1997, 111 Stat. 360–362, 366, 367, 373, 376, 377, 386, 387, 394, 400, 421–426, 442–444, 450, 463, 466, 472, 474; Pub. L. 105–277, div. J, title V, §5101(a), (b), (d)(1), Oct. 21, 1998, 112 Stat. 2681–913, 2681–914; Pub. L. 106–113, div. B, §1000(a)(6) [title II, §§201(k), 221(b)(1), 227(a), title III, §§303(a), 304(a), 321(k)(7)–(9), title V, §521], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, 1501A–351, 1501A–354, 1501A–360, 1501A–361, 1501A–367, 1501A–386; Pub. L. 106–554, §1(a)(6) [title I, §§101(a), 102(a), (b), 103(a), 105(a), (b), 112(a), 113(a), title IV, §§430(b), 431(a), title V, §§502(a), 541], Dec. 21, 2000, 114 Stat. 2763, 2763A–467, 2763A–468, 2763A–471, 2763A–473, 2763A–525, 2763A–529, 2763A–550; Pub. L. 108–173, title III, §303(i)(2), title IV, §§408(a), 414(f)(2), formerly 414(g)(2), 415(b), title V, §512(c), title VI, §§611(a), (b), (d)(2), 612(a), (b), 613(a), (b), 642(a), title VII, §§706(b), 736(a)(10), (11), (b)(3), (11), (12), (c)(4), title IX, §§901(b), 926(b)(1), 946(a), Dec. 8, 2003, 117 Stat. 2254, 2270, 2281, 2282, 2299, 2303–2305, 2322, 2339, 2355, 2356, 2374, 2396, 2424, renumbered Pub. L. 111–68, div. A, title I, §1501(e)(2), Oct. 1, 2009, 123 Stat. 2041; Pub. L. 109–171, title V, §§5004, 5112(a), (b), 5114(a)(1), (b), title VI, §6001(f)(1), Feb. 8, 2006, 120 Stat. 32, 43–45, 58; Pub. L. 110–173, title I, §114(a), Dec. 29, 2007, 121 Stat. 2501; Pub. L. 110–275, title I, §§101(a)(1), (b)(1), 125(b)(2), 143(a), (b)(5), (6), 144(a)(1), 152(b)(1)(A), (B), 153(b)(3)(B), 182(b), July 15, 2008, 122 Stat. 2496, 2497, 2519, 2542–2544, 2551, 2556, 2583; Pub. L. 110–355, §7(a), Oct. 8, 2008, 122 Stat. 3995; Pub. L. 111–148, title IV, §§4103(a), (b), 4104(a), title V, §5502(a)(1), title VI, §6402(g)(2), title X, §§10402(b), 10501(i)(1), (2)(A), Mar. 23, 2010, 124 Stat. 553, 557, 654, 759, 975, 997; Pub. L. 111–152, title I, §1301(a), (b), Mar. 30, 2010, 124 Stat. 1057; Pub. L. 112–40, title II, §261(a)(3)(B), Oct. 21, 2011, 125 Stat. 423; Pub. L. 112–96, title III, §3201(a)–(c), Feb. 22, 2012, 126 Stat. 191, 192; Pub. L. 113–185, §3(a)(1), Oct. 6, 2014, 128 Stat. 1968; Pub. L. 114–10, title V, §513, Apr. 16, 2015, 129 Stat. 171; Pub. L. 114–27, title VIII, §808(a), June 29, 2015, 129 Stat. 418; Pub. L. 114–40, §2(a), July 30, 2015, 129 Stat. 441; Pub. L. 114–113, div. O, title V, §504(b)(2), Dec. 18, 2015, 129 Stat. 3022; Pub. L. 114–255, div. A, title V, §5012(a), (c)(3), Dec. 13, 2016, 130 Stat.

1198, 1202; Pub. L. 115–123, div. E, title X, §§51004, 51006(a)(1), 51008(a), (b), Feb. 9, 2018, 132 Stat. 295–297; Pub. L. 115–271, title II, §§2002(a), (b), 2005(a), (b), Oct. 24, 2018, 132 Stat. 3925, 3926, 3928.)

APPLICABILITY OF AMENDMENT

Amendment of section by section 5012(a), (c)(3) of Pub. L. 114–255 applicable to items and services furnished on or after Jan. 1, 2021. See 2016 Amendment notes below.

AMENDMENT OF SUBSECTIONS (eee), (fff)

Pub. L. 115–123, div. E, title X, §51008, Feb. 9, 2018, 132 Stat. 297, made amendments to subsections (eee) and (fff) of this section applicable to items and services furnished on or after Jan. 1, 2024. After such effective date—

(1) Subsection (eee)(1), (2)(A), (B), and the introductory provisions of subsection (eee)(4)(A) will read as follows:

(1) The term “cardiac rehabilitation program” means a program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)).

(2) A program described in this paragraph is a program under which—

(A) items and services under the program are delivered—

(i) in a physician’s office;

(ii) in a hospital on an outpatient basis; or

(iii) in other settings determined appropriate by the Secretary;

(B) a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)) is immediately available and accessible for medical consultation and medical emergencies at all times items and services are being furnished under the program, except that, in the case of items and services furnished under such a program in a hospital, such availability shall be presumed; and

(4)(A) The term “intensive cardiac rehabilitation program” means a program (as described in paragraph (2)) that furnishes the items and services described in paragraph (3) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)) and has shown, in peer-reviewed published research, that it accomplished—

(2) Subsection (fff)(1) will read as follows:

(1) The term “pulmonary rehabilitation program” means a program (as described in subsection (eee)(2) with respect to a program under this subsection) that furnishes the items and services described in paragraph (2) under the supervision of a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)).

See 2018 Amendment notes below.

REFERENCES IN TEXT

Section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (s)(10)(A), is section 4071(b) of Pub. L. 100–203, which is set out as a note below.

Section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (s)(12), is section

4072(e) of Pub. L. 100-203, which is set out as a note below.

The Public Health Service Act, referred to in subsec. (v)(1)(M), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of this title. Titles VI and XVI of the Public Health Service Act are classified generally to subchapters IV (§291 et seq.) and XIV (§300q et seq.), respectively, of chapter 6A of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

Section 1395cc(a)(2)(B)(ii) of this title, referred to in subsec. (v)(4), was repealed by Pub. L. 101-239, title VI, §6017(2), Dec. 19, 1989, 103 Stat. 2165.

Section 329 of the Public Health Service Act, referred to in subsec. (aa)(2), was section 329 of act July 1, 1944, which was classified to section 254b of this title and was omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of chapter 6A of this title by Pub. L. 104-299, §2, Oct. 11, 1996, 110 Stat. 3626.

The Indian Self-Determination Act, referred to in subsec. (aa)(4)(D), is title I of Pub. L. 93-638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (aa)(4)(D), is Pub. L. 94-437, Sept. 30, 1976, 90 Stat. 1400. Title V of the Act is classified generally to subchapter IV (§1651 et seq.) of chapter 18 of Title 25. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

The Internal Revenue Code of 1986, referred to in subsec. (ss)(1)(A), is classified generally to Title 26, Internal Revenue Code.

Clause (II) of section 1395ww(d)(1)(B)(iv) of this title, referred to in subsec. (ccc)(2), was redesignated cl. (vi) of section 1395ww(d)(1)(B) by Pub. L. 114-255, div. C, title XV, §15008(a)(2)(B), Dec. 13, 2016, 130 Stat. 1321.

AMENDMENTS

2018—Subsec. (s)(2)(HH). Pub. L. 115-271, §2005(a), added subpar. (HH).

Subsec. (dd)(3)(B). Pub. L. 115-123, §51006(a)(1), substituted “, the nurse” for “or nurse” and inserted “, or the physician assistant (as defined in such subsection)” after “subsection (aa)(5)”.

Subsec. (ww)(1). Pub. L. 115-271, §2002(a)(1), substituted “paragraph (2),” for “paragraph (2) and” and inserted “and the furnishing of a review of any current opioid prescriptions (as defined in paragraph (4)),” after “upon the agreement with the individual.”

Subsec. (ww)(2)(N), (O). Pub. L. 115-271, §2002(a)(2), added subpar. (N) and redesignated former subpar. (N) as (O).

Subsec. (ww)(4). Pub. L. 115-271, §2002(a)(3), added par. (4).

Subsec. (eee)(1). Pub. L. 115-123, §51008(a)(1), struck out “physician-supervised” after “means a” and inserted “under the supervision of a physician (as defined in subsection (r)(1) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)))” before period at end.

Subsec. (eee)(2)(A)(iii). Pub. L. 115-123, §51008(a)(2)(A), substituted “Secretary;” for “Secretary.”

Subsec. (eee)(2)(B). Pub. L. 115-123, §51008(a)(2)(B), substituted “a physician (as defined in subsection (r)(1) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)))” for “a physician”.

Subsec. (eee)(4)(A). Pub. L. 115-123, §51008(a)(3), struck out “physician-supervised” after “means a” and inserted “under the supervision of a physician (as defined in subsection (r)(1) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)))” after “paragraph (3)”.

Subsec. (eee)(4)(B)(vii), (viii). Pub. L. 115-123, §51004, added cls. (vii) and (viii).

Subsec. (fff)(1). Pub. L. 115-123, §51008(b), struck out “physician-supervised” after “means a” and inserted “under the supervision of a physician (as defined in subsection (r)(1) or a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)))” before period at end.

Subsec. (hhh)(2)(G) to (I). Pub. L. 115-271, §2002(b), added subpars. (G) and (H) and redesignated former subpar. (G) as (I).

Subsec. (jjj). Pub. L. 115-271, §2005(b), added subsec. (jjj).

2016—Subsec. (m). Pub. L. 114-255, §5012(c)(3), inserted “and home infusion therapy (as defined in subsection (iii)(i))” after “furnished to an inpatient of a hospital” in concluding provisions.

Subsec. (s)(2)(GG). Pub. L. 114-255, §5012(a)(1), added subpar. (GG).

Subsec. (iii). Pub. L. 114-255, §5012(a)(2), added subsec. (iii).

2015—Subsec. (m)(5). Pub. L. 114-113, §504(b)(2), inserted “and applicable disposable devices (as defined in section 1395m(s)(2) of this title)” after “durable medical equipment”.

Subsec. (n). Pub. L. 114-40 inserted “and eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories” after “appropriate organizations”.

Subsec. (o)(7). Pub. L. 114-10 amended par. (7) generally. Prior to amendment, par. (7) read as follows:

“(7) provides the Secretary with a surety bond—

“(A) effective for a period of 4 years (as specified by the Secretary) or in the case of a change in the ownership or control of the agency (as determined by the Secretary) during or after such 4-year period, an additional period of time that the Secretary determines appropriate, such additional period not to exceed 4 years from the date of such change in ownership or control;

“(B) in a form specified by the Secretary; and

“(C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of \$50,000 or 10 percent of the aggregate amount of payments to the agency under this subchapter and subchapter XIX of this chapter for that year, as estimated by the Secretary that the Secretary determines is commensurate with the volume of the billing of the home health agency; and”.

Subsec. (s)(2)(F). Pub. L. 114-27 inserted before semicolon at end “, including such renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or provider of services paid under section 1395rr(b)(14) of this title to an individual with acute kidney injury (as defined in section 1395m(r)(2) of this title)”.

2014—Subsec. (dd)(4)(C). Pub. L. 113-185 added subpar. (C).

2012—Subsec. (v)(1)(T)(iv), (v). Pub. L. 112-96, §3201(a), substituted “fiscal years 2001 through 2012” for “a subsequent fiscal year” in cl. (iv) and added cl. (v).

Subsec. (v)(1)(V). Pub. L. 112-96, §3201(b)(1), substituted “and (beginning with respect to cost reporting periods beginning during fiscal year 2013) for covered skilled nursing services described in section 1395yy(e)(2)(A) of this title furnished by hospital providers of extended care services (as described in section 1395tt of this title)” for “with respect to cost reporting periods beginning on or after October 1, 2005” in introductory provisions.

Subsec. (v)(1)(V)(i). Pub. L. 112-96, §3201(b)(2), substituted “reduced by—” for “reduced by 30 percent of such amount otherwise allowable; and” and added subcls. (I) and (II).

Subsec. (v)(1)(V)(ii). Pub. L. 112-96, §3201(b)(3), substituted “such section—” for “such section shall not be reduced.” and added subcls. (I) to (IV).

Subsec. (v)(1)(W). Pub. L. 112-96, §3201(c), added subpar. (W).

2011—Subsecs. (v)(1)(G)(i), (w)(2). Pub. L. 112-40 substituted “quality improvement” for “quality control and peer review”.

2010—Subsec. (o)(7)(C). Pub. L. 111-148, §6402(g)(2), which directed amendment by inserting “that the Secretary determines is commensurate with the volume of the billing of the home health agency” before semicolon “at the end”, was executed by making the insertion before “; and” to reflect the probable intent of Congress.

Subsec. (s)(2)(K). Pub. L. 111-148, §4103(a)(2), substituted “subsections (ww)(1) and (hhh)” for “subsection (ww)(1)” in cls. (i) and (ii).

Subsec. (s)(2)(FF). Pub. L. 111-148, §4103(a)(1), added subpar. (FF).

Subsec. (aa)(3)(A). Pub. L. 111-148, §10501(i)(2)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: “services of the type described in subparagraphs (A) through (C) of paragraph (1) and services described in subsections (qq) and (vv); and”.

Pub. L. 111-148, §5502(a)(1), which directed general amendment of subpar. (A), was repealed by Pub. L. 111-148, §10501(i)(1).

Subsec. (ff)(3)(A). Pub. L. 111-152, §1301(b), inserted “other than in an individual’s home or in an inpatient or residential setting” before period at end.

Subsec. (ff)(3)(B)(iii), (iv). Pub. L. 111-152, §1301(a), added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (ddd). Pub. L. 111-148, §4104(a)(1), inserted “; preventive services” after “services” in heading.

Subsec. (ddd)(1). Pub. L. 111-148, §4104(a)(2), substituted “not described in subparagraph (A) or (C) of paragraph (3)” for “not otherwise described in this subchapter”.

Subsec. (ddd)(3). Pub. L. 111-148, §4104(a)(3), added par. (3).

Subsec. (hhh). Pub. L. 111-148, §4103(b), added subsec. (hhh).

Subsec. (hhh)(4)(G). Pub. L. 111-148, §10402(b), amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows:

“(G)(i) A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary’s coverage begins under part B of this subchapter and shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12-month period.

“(ii) The Secretary shall establish procedures to make beneficiaries aware of the option to select an initial preventive physical examination or personalized prevention plan services during the period of 12 months after the date that a beneficiary’s coverage begins under part B of this subchapter, which shall include information regarding any relevant differences between such services.”

2008—Subsec. (e). Pub. L. 110-275, §125(b)(2), in third sentence after par. (9), substituted “and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1395bb(a) of this title, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.” for “and (ii) is accredited by the Joint Commission on Accreditation of Hospitals, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of the Joint Commission on Accreditation of Hospitals”.

Subsec. (p). Pub. L. 110-275, §143(b)(5), struck out third sentence in concluding provisions, which read as follows: “The term ‘outpatient physical therapy services’ also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilita-

tion agency, or by a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient, subject to the conditions prescribed in this subsection.”

Subsec. (s)(2)(D). Pub. L. 110-275, §143(b)(6), inserted “, outpatient speech-language pathology services,” after “physical therapy services”.

Subsec. (s)(2)(F). Pub. L. 110-275, §153(b)(3)(B), inserted “, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1395rr(b)(14)(B) of this title)” before semicolon at end.

Subsec. (s)(2)(BB). Pub. L. 110-275, §101(a)(1)(A), added subpar. (BB).

Subsec. (s)(2)(CC), (DD). Pub. L. 110-275, §144(a)(1)(A), added subpars. (CC) and (DD).

Subsec. (s)(2)(EE). Pub. L. 110-275, §152(b)(1)(A), added subpar. (EE).

Subsec. (t)(2)(B). Pub. L. 110-275, §182(b), in concluding provisions, inserted “On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.” at end.

Subsec. (aa)(2). Pub. L. 110-355 substituted “4-year period” for “3-year period” in cl. (i) of concluding provisions.

Subsec. (ll)(2) to (4). Pub. L. 110-275, §143(a), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively.

Subsec. (ww)(1). Pub. L. 110-275, §101(b)(1)(A), inserted “body mass index,” after “weight”, struck out “, and an electrocardiogram” after “blood pressure”, and inserted “and end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual” after “paragraph (2)”.

Subsec. (ww)(2)(M), (N). Pub. L. 110-275, §101(b)(1)(B), added subpars. (M) and (N).

Subsec. (ww)(3). Pub. L. 110-275, §101(b)(1)(C), added par. (3).

Subsec. (ddd). Pub. L. 110-275, §101(a)(1)(B), added subsec. (ddd).

Subsecs. (eee), (fff). Pub. L. 110-275, §144(a)(1)(B), added subsecs. (eee) and (fff).

Subsec. (ggg). Pub. L. 110-275, §152(b)(1)(B), added subsec. (ggg).

2007—Subsec. (ccc). Pub. L. 110-173 added subsec. (ccc).

2006—Subsec. (s)(2)(AA). Pub. L. 109-171, §5112(a)(1), added subpar. (AA).

Subsec. (t)(2)(B)(ii)(I). Pub. L. 109-171, §6001(f)(1), inserted “(or its successor publications)” after “United States Pharmacopoeia-Drug Information”.

Subsec. (v)(1)(T). Pub. L. 109-171, §5004(b), substituted “section 1395l(t)(8)(B)” for “section 1395(t)(5)(B)” in introductory provisions.

Subsec. (v)(1)(V). Pub. L. 109-171, §5004(a), added subpar. (V).

Subsec. (aa)(3). Pub. L. 109-171, §5114(a)(1), substituted “and services described in subsections (qq) and (vv); and” for “, and” in subpar. (A) and “section 330” for “sections 329, 330, and 340” in subpar. (B) and inserted “by the center or by a health care professional under contract with the center” after “outpatient of a Federally qualified health center” in concluding provisions.

Subsec. (aa)(4)(A)(i), (ii)(II). Pub. L. 109-171, §5114(b), struck out “(other than subsection (h))” after “section 330”.

Subsec. (ww)(2)(L). Pub. L. 109-171, §5112(b), added subpar. (L).

Subsec. (bbb). Pub. L. 109-171, §5112(a)(2), added subsec. (bbb).

2003—Subsec. (d). Pub. L. 108-173, §901(b), added subsec. (d).

Subsec. (s)(2)(A). Pub. L. 108-173, §303(i)(2), inserted “(or would have been so included but for the applica-

tion of section 1395w-3b of this title” after “included in the physicians’ bills”.

Subsec. (s)(2)(K)(i). Pub. L. 108-173, §736(b)(11), substituted “, but” for “; and but”.

Pub. L. 108-173, §611(d)(2), inserted “and services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Subsec. (s)(2)(K)(ii). Pub. L. 108-173, §611(d)(2), inserted “and services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Subsec. (s)(2)(W). Pub. L. 108-173, §611(a), added subpar. (W).

Subsec. (s)(2)(X). Pub. L. 108-173, §612(a), added subpar. (X).

Subsec. (s)(2)(Y). Pub. L. 108-173, §613(a), added subpar. (Y).

Subsec. (s)(2)(Z). Pub. L. 108-173, §642(a)(1), added subpar. (Z).

Subsec. (s)(7). Pub. L. 108-173, §415(b), inserted “, subject to section 1395m(l)(14) of this title,” after “but”.

Subsec. (v)(1)(S)(ii)(III). Pub. L. 108-173, §736(b)(3), inserted closing parenthesis after “as defined in section 1395ww(d)(5)(D)(iii) of this title”.

Subsec. (v)(1)(U). Pub. L. 108-173, §414(f)(2), formerly §414(g)(2), as renumbered by Pub. L. 111-68, realigned margins.

Subsec. (v)(8). Pub. L. 108-173, §736(c)(4), realigned margins.

Subsec. (aa)(1)(B). Pub. L. 108-173, §736(b)(12), struck out second comma after “(as defined in subsection (hh)(1)).”

Subsec. (dd)(2)(A)(i). Pub. L. 108-173, §512(c), inserted “and services described in section 1395d(a)(5) of this title” before comma at end.

Subsec. (dd)(3)(B). Pub. L. 108-173, §408(a), inserted “or nurse practitioner (as defined in subsection (aa)(5))” after “the physician (as defined in subsection (r)(1))”.

Subsec. (dd)(5)(D), (E). Pub. L. 108-173, §946(a), added subpars. (D) and (E).

Subsec. (ee)(2)(D). Pub. L. 108-173, §926(b)(1), substituted “hospice care and post-hospital extended care services” for “hospice services” and inserted before period at end “and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this subchapter and that serve the area in which the patient resides”.

Subsec. (mm). Pub. L. 108-173, §736(a)(10), made technical amendment to heading.

Subsec. (tt)(1)(A), (2)(B). Pub. L. 108-173, §736(a)(11), substituted “critical access hospital” for “rural primary care hospital”.

Subsec. (ww). Pub. L. 108-173, §611(b), added subsec. (ww).

Subsec. (xx). Pub. L. 108-173, §612(b), added subsec. (xx).

Subsec. (yy). Pub. L. 108-173, §613(b), added subsec. (yy).

Subsec. (zz). Pub. L. 108-173, §642(a)(2), added subsec. (zz).

Subsec. (aaa). Pub. L. 108-173, §706(b), added subsec. (aaa).

2000—Subsec. (s)(2)(A), (B). Pub. L. 106-554, §1(a)(6) [title I, §112(a)], substituted “(including drugs and biologicals which are not usually self-administered by the patient)” for “(including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered)”.

Subsec. (s)(2)(J). Pub. L. 106-554, §1(a)(6) [title I, §113(a)], struck out provisions limiting application to drugs furnished within 12 months after the date of the transplant procedure for drugs furnished before 1995, to within 18 months after the date of the transplant procedure for drugs furnished during 1995, to within 24 months after the date of the transplant procedure for drugs furnished during 1996, to within 30 months after the date of the transplant procedure for drugs furnished during 1997, and to within 36 months after the date of

the transplant procedure plus additional number of months provided under section 1395k(b) for drugs furnished during any year after 1997.

Subsec. (s)(2)(U). Pub. L. 106-554, §1(a)(6) [title I, §102(a)], added subpar. (U).

Subsec. (s)(2)(V). Pub. L. 106-554, §1(a)(6) [title I, §105(a)], added subpar. (V).

Subsec. (t)(1). Pub. L. 106-554, §1(a)(6) [title IV, §430(b)], inserted “(including contrast agents)” after “only such drugs”.

Subsec. (v)(1)(L)(x). Pub. L. 106-554, §1(a)(6) [title V, §502(a)], struck out “2001,” after “2000,” and inserted at end “With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.”

Subsec. (v)(1)(T)(ii). Pub. L. 106-554, §1(a)(6) [title V, §541(1)], struck out “and” at end.

Subsec. (v)(1)(T)(iii). Pub. L. 106-554, §1(a)(6) [title V, §541(2)], substituted “during fiscal year 2000” for “during a subsequent fiscal year” and “, and” for period at end.

Subsec. (v)(1)(T)(iv). Pub. L. 106-554, §1(a)(6) [title V, §541(3)], added cl. (iv).

Subsec. (ff)(3)(B). Pub. L. 106-554, §1(a)(6) [title IV, §431(a)], substituted “entity that—” for “entity—”, added cls. (i) to (iii), and struck out former cls. (i) and (ii) which read as follows:

“(i) providing the services described in section 1916(c)(4) of the Public Health Service Act; and

“(ii) meeting applicable licensing or certification requirements for community mental health centers in the State in which it is located.”

Subsec. (nn)(1), (2). Pub. L. 106-554, §1(a)(6) [title I, §101(a)], substituted “2 years” for “3 years”.

Subsec. (pp)(1)(C). Pub. L. 106-554, §1(a)(6) [title I, §103(a)(1)], substituted “Screening colonoscopy” for “In the case of an individual at high risk for colorectal cancer, screening colonoscopy”.

Subsec. (pp)(2). Pub. L. 106-554, §1(a)(6) [title I, §103(a)(2)], substituted “An” for “In paragraph (1)(C), an”.

Subsec. (uu). Pub. L. 106-554, §1(a)(6) [title I, §102(b)], added subsec. (uu).

Subsec. (vv). Pub. L. 106-554, §1(a)(6) [title I, §105(b)], added subsec. (vv).

1999—Subsec. (o)(7). Pub. L. 106-113, §1000(a)(6) [title III, §304(a)], amended par. (7) generally. Prior to amendment, par. (7) read as follows: “provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000; and”.

Subsec. (p)(1). Pub. L. 106-113, §1000(a)(6) [title II, §221(b)(1)(A)], substituted “, (3), or (4)” for “or (3)”.

Subsec. (r)(4). Pub. L. 106-113, §1000(a)(6) [title II, §221(b)(1)(B)], inserted “for purposes of subsection (p)(1) and” after “but only”.

Subsec. (s)(2)(J)(v). Pub. L. 106-113, §1000(a)(6) [title II, §227(a)], inserted before semicolon at end “plus such additional number of months (if any) provided under section 1395k(b) of this title”.

Subsec. (s)(2)(T)(ii). Pub. L. 106-113, §1000(a)(6) [title III, §321(k)(7)], substituted semicolon for period at end.

Subsec. (v)(1)(L)(ix), (x). Pub. L. 106-113, §1000(a)(6) [title III, §303(a)], added cl. (ix) and redesignated former cl. (ix) as (x).

Subsec. (v)(1)(S)(ii)(I), (II). Pub. L. 106-113, §1000(a)(6) [title II, §201(k)], substituted “and until the first date that the prospective payment system under section 1395l(t) of this title is implemented” for “and during fiscal year 2000 before January 1, 2000”.

Subsec. (aa)(2)(I). Pub. L. 106-113, §1000(a)(6) [title III, §321(k)(8)], substituted semicolon for comma at end and realigned margins.

Subsec. (ee)(3). Pub. L. 106-113, §1000(a)(6) [title V, §521], added par. (3).

Subsec. (ss)(1)(G)(i). Pub. L. 106-113, §1000(a)(6) [title III, §321(k)(9)(B)], which directed substitution of “or” for “of”, was executed by making the substitution for “of” the second time appearing to reflect the probable intent of Congress.

Pub. L. 106-113, § 1000(a)(6) [title III, § 321(k)(9)(A)], substituted “owned” for “owed”.

1998—Subsec. (v)(1)(L)(i)(III) to (V). Pub. L. 105-277, § 5101(b), in subcl. (III) struck out “or” at end, in subcl. (IV) inserted “and before October 1, 1998,” after “1997,” and substituted “, or” for period at end, and added subcl. (V).

Subsec. (v)(1)(L)(v). Pub. L. 105-277, § 5101(a)(1), inserted “subject to clause (viii)(I),” before “the Secretary” in introductory provisions.

Subsec. (v)(1)(L)(vi)(I). Pub. L. 105-277, § 5101(a)(2), inserted “subject to clauses (viii)(II) and (viii)(III)” after “1994”.

Subsec. (v)(1)(L)(viii). Pub. L. 105-277, § 5101(a)(3), added cl. (viii).

Subsec. (v)(1)(L)(ix). Pub. L. 105-277, § 5101(d)(1), added cl. (ix).

1997—Subsec. (a). Pub. L. 105-33, § 4201(c)(1), substituted “critical access” for “rural primary care” in pars. (1) and (2).

Subsec. (b)(4). Pub. L. 105-33, § 4511(a)(2)(B), substituted “subsection (s)(2)(K)” for “clauses (i) or (iii) of subsection (s)(2)(K)”.

Subsec. (e). Pub. L. 105-33, § 4454(a)(1)(A), in fifth sentence after par. (9), substituted “includes a religious nonmedical health care institution (as defined in subsection (ss)(1)),” for “includes a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts,” and inserted “consistent with section 1395i-5 of this title” before the period.

Pub. L. 105-33, § 4201(c)(1), substituted “critical access” for “rural primary care” in last sentence.

Subsec. (h). Pub. L. 105-33, § 4432(b)(5)(D)(i), substituted “paragraphs (3), (6), and (7)” for “paragraphs (3) and (6)” in introductory provisions.

Subsec. (h)(7). Pub. L. 105-33, § 4432(b)(5)(D)(ii), inserted “, or by others under arrangements with them made by the facility” after “skilled nursing facilities”.

Subsec. (m). Pub. L. 105-33, § 4612(a), inserted at end of closing provisions “For purposes of paragraphs (1) and (4), the term ‘part-time or intermittent services’ means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1395f(a)(2)(C) and 1395n(a)(2)(A) of this title, ‘intermittent’ means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).”

Subsec. (n). Pub. L. 105-33, § 4105(b)(1), inserted before semicolon in first sentence “, and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual’s use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations)”.

Subsec. (o). Pub. L. 105-33, § 4312(b)(1)(D), inserted at end of closing provisions “The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.”

Subsec. (o)(7), (8). Pub. L. 105-33, § 4312(b)(1)(A)–(C), added par. (7) and redesignated former par. (7) as (8).

Subsec. (p). Pub. L. 105-33, § 4312(e)(2), inserted at end of closing provisions “The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.”

Subsec. (p)(4)(A)(v). Pub. L. 105-33, § 4312(e)(1), inserted “and provides the Secretary on a continuing basis with a surety bond in a form specified by the Secretary and in an amount that is not less than \$50,000,” after “as the Secretary may find necessary,”.

Subsec. (r)(5). Pub. L. 105-33, § 4513(a), struck out “demonstrated by x-ray to exist” following “(to correct a subluxation”.

Subsec. (s)(2)(K)(i). Pub. L. 105-33, §§ 4511(a)(2)(A)(i), 4512(a), struck out “(I) in a hospital, skilled nursing facility, or nursing facility (as defined in section 1396r(a) of this title), (II) as an assistant at surgery, or (III) in a rural area (as defined in section 1395ww(d)(2)(D) of this title) that is designated, under section 332(a)(1)(A) of the Public Health Service Act, as a health professional shortage area,” after “physician (as so defined)” and inserted at end “and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician’s professional service; and but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,”.

Subsec. (s)(2)(K)(ii). Pub. L. 105-33, § 4511(a)(1), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: “services which would be physicians’ services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner (as defined in subsection (aa)(5) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) in a skilled nursing facility or nursing facility (as defined in section 1396r(a) of this title) which the nurse practitioner is legally authorized to perform by the State in which the services are performed,”.

Subsec. (s)(2)(K)(iii), (iv). Pub. L. 105-33, § 4511(a)(2)(A)(ii), struck out cls. (iii) and (iv) which read as follows:

“(iii) services which would be physicians’ services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) in a rural area (as defined in section 1395ww(d)(2)(D) of this title) which the nurse practitioner or clinical nurse specialist is authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished as an incident to a physician’s professional service, and

“(iv) such services and supplies furnished as an incident to services described in clause (i) or (ii) as would be covered under subparagraph (A) if furnished as an incident to a physician’s professional service;”.

Subsec. (s)(2)(N) to (P). Pub. L. 105-33, § 4103(a)(1), struck out “and” at end of subpars. (N) and (O) and added subpar. (P).

Subsec. (s)(2)(R). Pub. L. 105-33, § 4104(a)(1)(A), added subpar. (R).

Subsec. (s)(2)(S). Pub. L. 105-33, § 4105(a)(1)(A), added subpar. (S).

Subsec. (s)(2)(T). Pub. L. 105-33, § 4557(a), added subpar. (T).

Subsec. (s)(12)(C). Pub. L. 105-33, § 4106(a)(1)(A), struck out “and” at end.

Subsec. (s)(14). Pub. L. 105-33, § 4102(c), inserted “and screening pelvic exam” after “screening pap smear”.

Subsec. (s)(15) to (17). Pub. L. 105-33, § 4106(a)(1)(B)–(D), added par. (15) and redesignated former pars. (15) and (16) as (16) and (17), respectively.

Subsec. (u). Pub. L. 105-33, § 4201(c)(1), substituted “critical access” for “rural primary care”.

Subsec. (v)(1)(H)(i). Pub. L. 105-33, § 4312(b)(2)(A), substituted “the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8)” for “the financial security requirement described in subsection (o)(7)”.

Subsec. (v)(1)(H)(ii). Pub. L. 105-33, § 4312(b)(2)(B), substituted “the surety bond requirement described in subsection (o)(7) and the financial security requirement described in subsection (o)(8) apply” for “the financial security requirement described in subsection (o)(7) applies”.

Subsec. (v)(1)(L)(i). Pub. L. 105-33, § 4602(a)(5), struck out closing provisions which read as follows: “of the mean of the labor-related and nonlabor per visit costs for free standing home health agencies.”

Subsec. (v)(1)(L)(i)(I). Pub. L. 105-33, § 4602(a)(1), (2), inserted “of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies” before comma at end and realigned margins.

Subsec. (v)(1)(L)(i)(II). Pub. L. 105-33, § 4602(a)(1), (3), substituted “of such mean,” for “, or” at end and realigned margins.

Subsec. (v)(1)(L)(i)(III). Pub. L. 105-33, § 4602(a)(1), (4), inserted “and before October 1, 1997,” after “July 1, 1987,” substituted “of such mean, or” for comma at end, and realigned margins.

Subsec. (v)(1)(L)(i)(IV). Pub. L. 105-33, § 4602(a)(5), added subcl. (IV).

Subsec. (v)(1)(L)(iii). Pub. L. 105-33, § 4604(b), substituted “service is furnished” for “agency is located”.

Pub. L. 105-33, § 4602(b), inserted “, or on or after July 1, 1997, and before October 1, 1997” after “July 1, 1996”.

Subsec. (v)(1)(L)(iv). Pub. L. 105-33, § 4601(a), added cl. (iv).

Subsec. (v)(1)(L)(v) to (vii). Pub. L. 105-33, § 4602(c), added cls. (v) to (vii).

Subsec. (v)(1)(O)(i). Pub. L. 105-33, § 4404(a)(1), struck out “and (if applicable) a return on equity capital” after “capital indebtedness” and substituted “provider of services” for “hospital or skilled nursing facility”, “clause (iii)” for “clause (iv)”, and “the historical cost of the asset, as recognized under this subchapter, less depreciation allowed, to the owner of record as of August 5, 1997 (or, in the case of an asset not in existence as of August 5, 1997, the first owner of record of the asset after August 5, 1997).” for “the lesser of the allowable acquisition cost of such asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of such date, the first owner of record of the asset after such date), or the acquisition cost of such asset to the new owner.”

Subsec. (v)(1)(O)(ii) to (iv). Pub. L. 105-33, § 4404(a)(2), (3), redesignated cls. (iii) and (iv) as (ii) and (iii), respectively, and struck out former cl. (ii) which read as follows: “Such regulations shall provide for recapture of depreciation in the same manner as provided under the regulations in effect on June 1, 1984.”

Subsec. (v)(1)(S)(i)(I), (II). Pub. L. 105-33, § 4522, substituted “through 1999 and during fiscal year 2000 before January 1, 2000” for “through 1998”.

Subsec. (v)(1)(S)(ii)(III). Pub. L. 105-33, § 4201(c)(1), substituted “critical access” for “rural primary care”.

Subsec. (v)(1)(T). Pub. L. 105-33, § 4451, added subpar. (T).

Subsec. (v)(1)(U). Pub. L. 105-33, § 4531(a)(1), added subpar. (U).

Subsec. (v)(7)(D). Pub. L. 105-33, § 4432(b)(5)(E), inserted “subsections (a) through (c) of” before “section 1395y of this title”.

Subsec. (v)(8). Pub. L. 105-33, § 4320, added par. (8).

Subsec. (w). Pub. L. 105-33, § 4201(c)(1), substituted “critical access” for “rural primary care” wherever appearing.

Subsec. (y). Pub. L. 105-33, § 4454(a)(1)(B)(i), substituted “Extended care in religious nonmedical health care institutions” for “Post-hospital extended care in Christian Science skilled nursing facilities” in heading.

Subsec. (y)(1). Pub. L. 105-33, § 4454(a)(1)(B)(iii), which directed the amendment of this subsec. by inserting “consistent with section 1395i-5 of this title” before the period, was executed by making the insertion in par. (1) to reflect the probable intent of Congress.

Pub. L. 105-33, § 4454(a)(1)(B)(ii), substituted “includes a religious nonmedical health care institution (as defined in subsection (ss)(1)),” for “includes a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts,”.

Subsec. (aa)(2). Pub. L. 105-33, § 4205(d)(3)(A), in second sentence of concluding provisions inserted before period at end “if it is determined, in accordance with

criteria established by the Secretary in regulations, to be essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinic”.

Pub. L. 105-33, § 4205(d)(1), (2), in cl. (i) of first sentence of concluding provisions substituted “Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 3-year period, has been designated” for “Bureau of the Census) and that is designated” and “personal health services or designated by the Secretary” for “personal health services, or that is designated by the Secretary”.

Subsec. (aa)(2)(I). Pub. L. 105-33, § 4205(b)(1), amended subpar. (I) generally. Prior to amendment, subpar. (I) read as follows: “has appropriate procedures for review of utilization of clinic services to the extent that the Secretary determines to be necessary and feasible;”.

Subsec. (aa)(5). Pub. L. 105-33, § 4511(d), designated existing provisions as subpar. (A), substituted “The term ‘physician assistant’ and the term ‘nurse practitioner’ mean, for purposes of this subchapter, a physician assistant or nurse practitioner who performs” for “The term ‘physician assistant’, the term ‘nurse practitioner’, and the term ‘clinical nurse specialist’ mean, for purposes of this subchapter, a physician assistant, nurse practitioner, or clinical nurse specialist who performs”, and added subpar. (B).

Subsec. (aa)(7)(B). Pub. L. 105-33, § 4205(c)(1), inserted before period at end “, or if the facility has not yet been determined to meet the requirements (including subparagraph (J) of the first sentence of paragraph (2)) of a rural health clinic”.

Subsec. (cc)(2). Pub. L. 105-33, § 4312(d)(4), inserted concluding provisions.

Subsec. (cc)(2)(I), (J). Pub. L. 105-33, § 4312(d)(1)-(3), added subpar. (I) and redesignated former subpar. (I) as (J).

Subsec. (dd)(1)(I). Pub. L. 105-33, § 4444(a), added subpar. (I).

Subsec. (dd)(2)(A)(ii)(I). Pub. L. 105-33, § 4445(1), substituted “subparagraphs (A), (C), and (H)” for “subparagraphs (A), (C), (F), and (H)”.

Subsec. (dd)(2)(B)(i). Pub. L. 105-33, § 4445(2), in concluding provisions, inserted “or, in the case of a physician described in subclause (I), under contract with” after “employed by”.

Subsec. (dd)(5)(B). Pub. L. 105-33, § 4446(1), inserted “or (C)” after “subparagraph (A)” in two places.

Subsec. (dd)(5)(C). Pub. L. 105-33, § 4446(2), added subpar. (C).

Subsec. (ee)(2)(D). Pub. L. 105-33, § 4321(a)(1), inserted before period at end “, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available”.

Subsec. (ee)(2)(H). Pub. L. 105-33, § 4321(a)(2), added subpar. (H).

Subsec. (mm). Pub. L. 105-33, § 4201(c)(2), amended heading and text of subsec. (mm) generally. Prior to amendment, text read as follows:

“(1) The term ‘rural primary care hospital’ means a facility designated by the Secretary as a rural primary care hospital under section 1395i-4(i)(2) of this title.

“(2) The term ‘inpatient rural primary care hospital services’ means items and services, furnished to an inpatient of a rural primary care hospital by such a hospital, that would be inpatient hospital services if furnished to an inpatient of a hospital by a hospital.

“(3) The term ‘outpatient rural primary care hospital services’ means medical and other health services furnished by a rural primary care hospital.”

Subsec. (nn). Pub. L. 105-33, § 4102(a), substituted “Screening pap smear; screening pelvic exam” for “Screening pap smear” in heading, designated existing provisions as par. (1), inserted “or vaginal” after “cervical” in two places, substituted “3 years, or during the preceding year in the case of a woman described in paragraph (3).” for “3 years (or such shorter period as

the Secretary may specify in the case of a woman who is at high risk of developing cervical or vaginal cancer (as determined pursuant to factors identified by the Secretary).”, and added pars. (2) and (3).

Subsec. (oo). Pub. L. 105-33, §4103(a)(2), added subsec. (oo).

Subsec. (pp). Pub. L. 105-33, §4104(a)(1)(B), added subsec. (pp).

Subsec. (qq). Pub. L. 105-33, §4105(a)(1)(B), added subsec. (qq).

Subsec. (rr). Pub. L. 105-33, §4106(a)(2), added subsec. (rr).

Subsec. (ss). Pub. L. 105-33, §4454(a)(1)(C), added subsec. (ss).

Subsec. (tt). Pub. L. 105-33, §4611(b), added subsec. (tt).

1996—Subsec. (aa)(4)(A)(i). Pub. L. 104-299 substituted “section 330 (other than subsection (h))” for “section 329, 330, or 340”.

Subsec. (aa)(4)(A)(ii)(II). Pub. L. 104-299 which directed amendment of subcl. (I) by substituting “section 330 (other than subsection (h))” for “section 329, 330, or 340”, was executed to subcl. (II) to reflect the probable intent of Congress.

1994—Subsec. (a)(1). Pub. L. 103-432, §102(g)(4)(A), substituted “inpatient hospital services, inpatient rural primary care hospital services” for “inpatient hospital services”.

Subsec. (a)(2). Pub. L. 103-432, §102(g)(4)(B), substituted “hospital or rural primary care hospital” for “hospital”.

Subsec. (b)(3). Pub. L. 103-432, §147(f)(3), made technical amendment to Pub. L. 101-508, §4157(a). See 1990 Amendment note below.

Subsec. (b)(4). Pub. L. 103-432, §147(f)(3), made technical amendment to Pub. L. 101-508, §4157(a). See 1990 Amendment note below.

Pub. L. 103-432, §147(e)(4), substituted “clauses (i) or (iii) of subsection (s)(2)(K)” for “subsection (s)(2)(K)(i)”.

Subsec. (e)(4). Pub. L. 103-432, §104, substituted “physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;” for “physician;”.

Subsec. (h)(3). Pub. L. 103-432, §146(b)(1), substituted “or occupational therapy or speech-language pathology services” for “, occupational, or speech therapy”.

Subsec. (m)(2). Pub. L. 103-432, §146(b)(2), substituted “or occupational therapy or speech-language pathology services” for “, occupational, or speech therapy”.

Subsec. (m)(5). Pub. L. 103-432, §147(f)(6)(B)(ii), substituted “and a covered osteoporosis drug (as defined in subsection (kk)), but excluding other drugs” for “but excluding drugs”.

Subsec. (p). Pub. L. 103-432, §146(b)(3), substituted “speech-language pathology services” for “speech pathology services” after “term ‘outpatient physical therapy services’ also includes” in third sentence of closing provisions.

Subsec. (s)(2)(K)(iii). Pub. L. 103-432, §147(e)(1), made an amendment identical to that made by Pub. L. 101-508, §4161(a)(5)(A), substituting “subsection (aa)(5)” for “subsection (aa)(3)” and “subsection (aa)(6)” for “subsection (aa)(4)”.

Subsec. (s)(2)(N). Pub. L. 103-432, §147(f)(6)(B)(iii)(I), inserted “and” at end.

Subsec. (s)(2)(O), (P). Pub. L. 103-432, §147(f)(6)(B)(iii)(II), redesignated subpar. (P) as (O) and struck out former subpar. (O) which read as follows: “a covered osteoporosis drug and its administration (as defined in subsection (jj) of this section) furnished on or after January 1, 1991, and on or before December 31, 1995; and”.

Subsec. (s)(3). Pub. L. 103-432, §145(b), inserted “and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act” after “necessary”.

Subsec. (v)(1)(L)(iii). Pub. L. 103-432, §158(a)(1), substituted “and determined using the survey of the most recent available wages and wage-related costs of hospitals” for “as of such date to hospitals”.

Subsec. (aa)(2). Pub. L. 103-432, §147(f)(4)(A), in last sentence of closing provisions, substituted “approval as such a clinic” for “certification as such a clinic” and “Secretary’s approval or disapproval” for “the Secretary’s approval or disapproval of the certification”.

Subsec. (aa)(5). Pub. L. 103-432, §147(e)(5), substituted “this subchapter” for “this chapter”.

Subsec. (cc)(1)(B). Pub. L. 103-432, §146(b)(4), substituted “speech-language pathology services” for “speech pathology services”.

Subsec. (dd)(1)(B). Pub. L. 103-432, §146(b)(5), substituted “therapy, or speech-language pathology services” for “therapy or speech-language pathology”.

Subsec. (ee)(2)(D). Pub. L. 103-432, §107(a), inserted “, including hospice services,” after “post-hospital services”.

Subsec. (jj). Pub. L. 103-432, §147(f)(6)(E), redesignated subsec. (jj), defining “covered osteoporosis drug”, as (kk).

Pub. L. 103-432, §147(f)(6)(A), (B)(i), amended subsec. (jj), defining “covered osteoporosis drug”, in introductory provisions, by striking out “a bone fracture related to” before “post-menopausal osteoporosis” and substituting “individual by a home health agency if” for “individual if”, and in par. (1), by substituting “individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual” for “patient”.

Subsec. (kk). Pub. L. 103-432, §147(f)(6)(E), redesignated subsec. (jj), defining “covered osteoporosis drug”, as (kk).

Subsec. (ll). Pub. L. 103-432, §146(a), added subsec. (ll).

1993—Subsec. (s)(2)(J). Pub. L. 103-66, §13565, substituted “subchapter, but only in the case of drugs furnished—” and cls. (i) to (v) for “subchapter, within 1 year after the date of the transplant procedure;”.

Subsec. (s)(2)(P). Pub. L. 103-66, §13566(b), substituted “dialysis” for “home dialysis” and realigned margin.

Subsec. (s)(2)(Q). Pub. L. 103-66, §13553(a), added subpar. (Q).

Subsec. (t). Pub. L. 103-66, §13553(b), designated existing provisions as par. (1), inserted “and paragraph (2)”, and added par. (2).

Subsec. (v)(1)(B). Pub. L. 103-66, §13503(c)(1), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “Such regulations in the case of extended care services furnished by proprietary facilities shall include provision for specific recognition of a reasonable return on equity capital, including necessary working capital, invested in the facility and used in the furnishing of such services, in lieu of other allowances to the extent that they reflect similar items. The rate of return recognized pursuant to the preceding sentence for determining the reasonable cost of any services furnished in any cost reporting period shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.”

Subsec. (v)(1)(L)(ii). Pub. L. 103-66, §13564(b)(1), struck out “, with appropriate adjustment for administrative and general costs of hospital-based agencies” after “discipline specific basis”.

Subsec. (v)(1)(L)(iii). Pub. L. 103-66, §13564(a)(2), substituted “thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996)” for “thereafter”.

Subsec. (v)(1)(S)(ii)(I). Pub. L. 103-66, §13521, substituted “fiscal years 1992 through 1998” for “fiscal year 1992, 1993, 1994, or 1995”.

Subsec. (v)(1)(S)(ii)(II). Pub. L. 103-66, §13522, substituted “fiscal years 1991 through 1998” for “fiscal years 1991, 1992, 1993, 1994, or 1995”.

Subsec. (aa)(4)(D). Pub. L. 103-66, §13556(a), added subpar. (D).

Subsec. (gg)(2). Pub. L. 103-66, §13554(a), substituted a period for “, and performs services in the area of man-

agement of the care of mothers and babies throughout the maternity cycle.”

1990—Subsec. (b)(3). Pub. L. 101-508, §4157(a)(1), as amended by Pub. L. 103-432, §147(f)(3), struck out “(including clinical psychologist (as defined by the Secretary))” after “the hospital or by others”.

Subsec. (b)(4). Pub. L. 101-508, §4157(a)(2), as amended by Pub. L. 103-432, §147(f)(3), substituted “, services described by subsection (s)(2)(K)(i), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and” for “and anesthesia services provided by a certified registered nurse anesthetist; and”.

Subsec. (n). Pub. L. 101-508, §4152(a)(2), inserted at end “With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.”

Subsec. (s)(2)(E). Pub. L. 101-508, §4161(a)(1), inserted “and Federally qualified health center services” after “clinic services”.

Subsec. (s)(2)(H)(i). Pub. L. 101-508, §4161(a)(5)(A), substituted “subsection (aa)(5)” for “subsection (aa)(3)”.

Subsec. (s)(2)(K)(i). Pub. L. 101-597 substituted “health professional shortage area” for “health manpower shortage area”.

Pub. L. 101-508, §4161(a)(5)(A), substituted “subsection (aa)(5)” for “subsection (aa)(3)”.

Subsec. (s)(2)(K)(ii). Pub. L. 101-508, §4161(a)(5)(A), substituted “subsection (aa)(5)” for “subsection (aa)(3)” and “subsection (aa)(6)” for “subsection (aa)(4)”.

Subsec. (s)(2)(K)(iii). Pub. L. 101-508, §4161(a)(5)(A), substituted “subsection (aa)(5)” for “subsection (aa)(3)” and “subsection (aa)(6)” for “subsection (aa)(4)”.

Pub. L. 101-508, §4155(a)(3), added cl. (iii). Former cl. (iii) redesignated (iv).

Subsec. (s)(2)(K)(iv). Pub. L. 101-508, §4155(a)(2), redesignated cl. (iii) as (iv).

Subsec. (s)(2)(O). Pub. L. 101-508, §4156(a)(1), added subpar. (O).

Subsec. (s)(2)(P). Pub. L. 101-508, §4201(d)(1), added subpar. (P).

Subsec. (s)(8). Pub. L. 101-508, §4153(b)(2)(A), inserted “, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens” after “such devices”.

Subsec. (s)(13). Pub. L. 101-508, §4163(a)(1), added par. (13).

Subsec. (v)(1)(E). Pub. L. 101-508, §4008(h)(2)(A)(i), substituted “the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this subchapter) of such facilities” for “the costs of such facilities” in second sentence.

Subsec. (v)(1)(L)(iii). Pub. L. 101-508, §4207(d)(1), formerly §4027(d)(1), as renumbered by Pub. L. 103-432, §160(d)(4), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: “In establishing limits under this subparagraph, the Secretary shall—

“(I) utilize a wage index that is based on verified wage data obtained from home health agencies, and

“(II) base such limits on the most recent verified wage data available, which data may be for cost reporting periods beginning no earlier than July 1, 1985. In the case of a home health agency that refuses to provide data, or deliberately provides false data, respecting wages for purposes of this clause upon the request of the Secretary, the Secretary may withhold up to 5 percent of the amount of the payments otherwise payable to the agency under this subchapter until such date as the Secretary determines that such data has been satisfactorily provided.”

Subsec. (v)(1)(S)(ii)(I). Pub. L. 101-508, §4151(a)(1), inserted before period at end “, by 15 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1991, and by 10 percent for payments attributable to portions of cost reporting pe-

riods occurring during fiscal year 1992, 1993, 1994, or 1995”.

Subsec. (v)(1)(S)(ii)(II). Pub. L. 101-508, §4151(b)(1)(D), added subcl. (II). Former subcl. (II) redesignated (III).

Pub. L. 101-508, §4151(b)(1)(A), substituted “Subclauses (I) and (II)” for “Subclause (I)” and “costs of hospital outpatient services provided by any hospital” for “capital-related costs of any hospital”.

Pub. L. 101-508, §4151(a)(2), substituted “section 1395ww(d)(5)(D)(iii) of this title or a rural primary care hospital (as defined in subsection (mm)(1))” for “section 1395ww(d)(5)(D)(iii) of this title”.

Subsec. (v)(1)(S)(ii)(III). Pub. L. 101-508, §4151(b)(1)(C), redesignated former subcl. (II) as (III). Former subcl. (III) redesignated (IV).

Pub. L. 101-508, §4151(b)(1)(B), substituted “subclauses (I) and (II)” for “subclause (I)” and “the costs reflected” for “capital-related costs reflected”.

Subsec. (v)(1)(S)(ii)(IV). Pub. L. 101-508, §4151(b)(1)(C), redesignated subcl. (III) as (IV).

Subsec. (aa). Pub. L. 101-508, §4161(a)(2)(A), inserted “and Federally qualified health center services” after “clinic services” in heading.

Subsec. (aa)(1)(B). Pub. L. 101-508, §4161(a)(5)(B), substituted “paragraph (5)” for “paragraph (3)”.

Subsec. (aa)(2). Pub. L. 101-597 substituted “health professional shortage area” for “health manpower shortage area” in second sentence.

Pub. L. 101-508, §4161(b)(1), inserted at end “If a State agency has determined under section 1395aa(a) of this title that a facility is a rural health clinic and the facility has applied to the Secretary for certification as such a clinic, the Secretary shall notify the facility of the the Secretary’s approval or disapproval of the certification not later than 60 days after the date of the State agency determination or the application (whichever is later).”

Subsec. (aa)(3). Pub. L. 101-508, §4161(a)(2)(C), added par. (3). Former par. (3) redesignated (5).

Pub. L. 101-508, §4161(a)(2)(B), which directed amendment of par. (3) by substituting “the previous provisions of this subsection” for “paragraphs (1) and (2)”, could not be executed because the words “paragraphs (1) and (2)” did not appear after amendment by Pub. L. 101-508, §4155(d). See below.

Pub. L. 101-508, §4155(d), substituted “The term ‘physician assistant’, the term ‘nurse practitioner’, and the term ‘clinical nurse specialist’ mean, for purposes of this chapter, a physician assistant, nurse practitioner, or clinical nurse specialist who performs” for “The term ‘physician assistant’ and the term ‘nurse practitioner’ mean, for the purposes of paragraphs (1) and (2), a physician assistant or nurse practitioner who performs”.

Subsec. (aa)(4) to (6). Pub. L. 101-508, §4161(a)(2)(B), (C), added par. (4) and redesignated former pars. (3) and (4) as (5) and (6), respectively.

Subsec. (aa)(7). Pub. L. 101-508, §4161(b)(2), added par. (7).

Subsec. (ff)(3). Pub. L. 101-508, §4162(a), designated existing provision as subpar. (A), substituted “outpatients or by a community mental health center (as defined in subparagraph (B)),” for “outpatients”, and added subpar. (B).

Subsec. (jj). Pub. L. 101-508, §4163(a)(2), added subsec. (jj) defining “screening mammography”.

Pub. L. 101-508, §4156(a)(2), added subsec. (jj) defining “covered osteoporosis drug”.

1989—Subsec. (a). Pub. L. 101-234, §101(a), repealed Pub. L. 100-360, §104(d)(4)(A), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (e). Pub. L. 101-239, §6003(g)(3)(D)(x)(I), inserted at end “The term ‘hospital’ does not include, unless the context otherwise requires, a rural primary care hospital (as defined in subsection (mm)(1)).”

Pub. L. 101-234, §101(a), repealed Pub. L. 100-360, §104(d)(4)(B), and provided that the provisions of law amended or repealed by such section are restored or re-

vived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (i). Pub. L. 101-234, §201(a), repealed Pub. L. 100-360, §104(d)(4)(C), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (m). Pub. L. 101-234, §201(a), repealed Pub. L. 100-360, §206(a), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (m)(5). Pub. L. 101-239, §6112(e)(1), amended par. (5) generally. Prior to amendment, par. (5) read as follows: "medical supplies (other than drugs and biologicals) and durable medical equipment, while under such a plan;"

Subsec. (s). Pub. L. 101-239, §6141(a)(1), substituted ", including a laboratory that is part of" for "which is independent of a physician's office, a laboratory not independent of a physician's office that has a volume of clinical diagnostic laboratory tests exceeding 5,000 per year," in provisions following par. (14).

Subsec. (s)(2)(H)(ii). Pub. L. 101-239, §6113(b)(2)(A), substituted "subsection (hh)(2)" for "subsection (hh)".

Subsec. (s)(2)(J). Pub. L. 101-239, §6114(a)(1), struck out "and" at end.

Pub. L. 101-234, §201(a), repealed Pub. L. 100-360, §202(a)(1), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (s)(2)(K). Pub. L. 101-239, §6114(a)(2), added cl. (ii), redesignated former cl. (ii) as (iii), and substituted "to services described in clause (i) or (ii)" for "to such services" in cl. (iii).

Subsec. (s)(2)(N). Pub. L. 101-239, §6113(b)(1), added subpar. (N).

Subsec. (s)(12). Pub. L. 101-239, §6131(a)(2), inserted "with inserts" after "custom molded shoes" in introductory provisions.

Subsec. (s)(13). Pub. L. 101-234, §201(a), which repealed Pub. L. 100-360, §204(a)(1)(B)-(D), and directed that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, was executed by striking out par. (13) as added by Pub. L. 100-360, §204(a)(1)(B)-(D), but former par. (13) which was redesignated (14) was not restored in view of intervening redesignation as (15) by Pub. L. 101-239, §6115(a)(1)(C), see 1988 Amendment note below.

Subsec. (s)(14). Pub. L. 101-239, §6115(a)(1)(A), (B), (D), added par. (14). Former par. (14) redesignated (15).

Pub. L. 101-234, §201(a), which repealed Pub. L. 100-360, §204(a)(1)(A), and directed that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, was not executed in view of intervening redesignation of par. (14) as (15) by Pub. L. 101-239, §6115(a)(1)(C), see 1988 Amendment note below.

Subsec. (s)(15). Pub. L. 101-239, §6115(a)(1)(C), redesignated par. (14) as (15). Former par. (15) redesignated (16).

Pub. L. 101-234, §201(a), which repealed Pub. L. 100-360, §204(a)(1)(A), and directed that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, was not executed in view of intervening redesignation of par. (15) as (16) by Pub. L. 101-239, §6115(a)(1)(C), see 1988 Amendment note below.

Subsec. (s)(16). Pub. L. 101-239, §6141(a)(2), (3), added subpar. (A) and designated existing provisions as subpar. (B).

Pub. L. 101-239, §6115(a)(1)(C), redesignated par. (15) as (16).

Subsec. (t). Pub. L. 101-234, §201(a), repealed Pub. L. 100-360, §202(a)(2), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (u). Pub. L. 101-239, §6003(g)(3)(C)(i), inserted "rural primary care hospital," after "hospital,"

Pub. L. 101-234, §201(a), repealed Pub. L. 100-360, §203(e)(1), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (v)(1)(G)(i). Pub. L. 101-234, §101(a), repealed Pub. L. 100-360, §104(d)(4)(D), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (v)(1)(S). Pub. L. 101-239, §6110, designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (v)(2)(A), (3). Pub. L. 101-234, §101(a), repealed Pub. L. 100-360, §104(d)(4)(D), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (w)(1). Pub. L. 101-239, §6003(g)(3)(D) (x)(II), inserted "rural primary care hospital," after "hospital,"

Subsec. (w)(2). Pub. L. 101-239, §6003(g)(3)(D) (x)(III), substituted "hospital or rural primary care hospital" for "hospital" in six places.

Subsec. (y). Pub. L. 101-234, §101(a), repealed Pub. L. 100-360, §104(d)(4)(E), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (aa)(1)(B). Pub. L. 101-239, §6213(b), substituted "(as defined in paragraph (3)), by" for "(as defined in paragraph (3)), or by" and inserted "or by a clinical social worker (as defined in subsection (hh)(1))," after "Secretary".

Subsec. (aa)(2). Pub. L. 101-239, §6213(c), in second sentence substituted "designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services, or that is designated by the Secretary" for "designated by the Secretary", "section 330(b)(3) or 1302(7) of the Public Health Service Act," for "section 1302(7) of the Public Health Service Act or", and "medical care manpower, (III) as a high impact area described in section 329(a)(5) of that Act, or (IV) as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act," for "medical care manpower,".

Subsec. (aa)(2)(J), (K). Pub. L. 101-239, §6213(a), added subpar. (J) and redesignated former subpar. (J) as (K).

Subsec. (aa)(4). Pub. L. 101-239, §6114(d), added par. (4).

Subsec. (hh). Pub. L. 101-239, §6113(b)(2)(B), inserted "clinical social worker services" after "social worker" in heading, redesignated existing provisions as par. (1), redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, in subpar. (C), redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, in cl. (ii), redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, and added par. (2).

Subsec. (ii). Pub. L. 101-239, §6113(a), struck out "on-site at a community mental health center (as such term is used in the Public Health Service Act), and such services that are necessarily furnished off-site (other than at an off-site office of such psychologist) as part of a treatment plan because of the inability of the individual furnished such services to travel to the center by reason of physical or mental impairment, because of institutionalization, or because of similar circumstances of the individual," after "as defined by the Secretary".

Subsecs. (jj) to (ll). Pub. L. 101-234, §201(a), repealed Pub. L. 100-360, §§203(b), 204(a)(2), 205(b), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 Amendment notes below.

Subsec. (mm). Pub. L. 101-239, §6003(g)(3)(A), added subsec. (mmm).

Subsec. (mm)(3). Pub. L. 101-239, §6116(a)(1), added par. (3).

Subsec. (nn). Pub. L. 101-239, §6115(a)(2), added subsec. (nn).

1988—Subsec. (a). Pub. L. 100-360, §104(d)(4)(A), struck out subsec. (a) which defined “spell of illness”.

Subsec. (a)(2). Pub. L. 100-360, §411(l)(1)(B)(i), (ii), redesignated and amended Pub. L. 100-203, §4201(d)(1), see 1987 Amendment note below.

Subsec. (e). Pub. L. 100-360, §104(d)(4)(B), substituted “and paragraph (7) of this subsection” for “paragraph (7) of this subsection, and subsection (i) of this section” in introductory provisions, struck out second sentence which read as follows: “For purposes of subsection (a)(2), such term includes any institution which meets the requirements of paragraph (1) of this subsection.”, substituted “and section 1395f(f)(2) of this title” for “section 1395f(f)(2) of this title, and subsection (i) of this section” in third sentence, and struck out “, except for purposes of subsection (a)(2),” after “such term shall not” in fifth sentence.

Subsec. (i). Pub. L. 100-360, §104(d)(4)(C), struck out subsec. (i) which defined “post-hospital extended care services”.

Subsec. (m). Pub. L. 100-360, §206(a), inserted at end “For purposes of paragraphs (1) and (4) and sections 1395f(a)(2)(C) and 1395n(a)(2)(A) of this title, nursing care and home health aide services shall be considered to be provided or needed on an ‘intermittent’ basis if they are provided or needed less than 7 days each week and, in the case they are provided or needed for 7 days each week, if they are provided or needed for a period of up to 38 consecutive days.”

Subsec. (n). Pub. L. 100-360, §411(l)(1)(C), as added by Pub. L. 100-485, §608(d)(27)(B), added Pub. L. 100-203, §4201(d)(5), see 1987 Amendment note below.

Pub. L. 100-360, §411(l)(1)(B)(iii), added Pub. L. 100-203, §4201(d)(2), see 1987 Amendment note below.

Pub. L. 100-360, §411(d)(1)(B)(i), inserted “; except that such term does not include such equipment furnished by a supplier who has used, for the demonstration and use of specific equipment, an individual who has not met such minimum training standards as the Secretary may establish with respect to the demonstration and use of such specific equipment” before period at end.

Subsec. (p). Pub. L. 100-647, §8424(a), inserted at end “Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this subchapter, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician.”

Subsec. (s). Pub. L. 100-360, §411(g)(3)(H), inserted a comma before “year” in provisions immediately preceding par. (13).

Subsec. (s)(2)(H)(ii). Pub. L. 100-360, §411(h)(5)(A), amended Pub. L. 100-203, §4074(a), see 1987 Amendment note below.

Subsec. (s)(2)(J). Pub. L. 100-360, §202(a)(1), amended subpar. (J) generally, substituting “covered outpatient drugs (as defined in subsection (t) of this section); and” for former provision which related to prescription drugs used in immunosuppressive therapy.

Subsec. (s)(2)(K)(i). Pub. L. 100-360, §411(h)(6), amended Pub. L. 100-203, §4076(a), see 1987 Amendment note below.

Subsec. (s)(2)(K)(i)(I). Pub. L. 100-485, §608(d)(23)(B), substituted “nursing facility (as defined in section 1396r(a) of this title)” for “intermediate care facility (as defined in section 1396d(c) of this title)”.

Subsec. (s)(2)(M). Pub. L. 100-360, §411(h)(7)(A), made technical amendment to directory language of Pub. L. 100-203, §4077(b)(1), see 1987 Amendment note below.

Subsec. (s)(10)(A). Pub. L. 100-360, §411(h)(2), inserted “, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987,” before “influenza vaccine”.

Subsec. (s)(12). Pub. L. 100-360, §411(h)(3)(A), inserted “subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987,” in introductory provisions.

Subsec. (s)(13). Pub. L. 100-360, §204(a)(1)(B)-(D), added par. (13) relating to screening mammography (as defined in subsection (kk) of this section). Former par. (13) redesignated (14).

Subsec. (s)(14). Pub. L. 100-360, §204(a)(1)(A), redesignated par. (13) as (14). Former par. (14) redesignated (15).

Subsec. (s)(15). Pub. L. 100-360, §411(i)(4)(C)(iii), amended directory language of Pub. L. 100-203, §4085(i)(11), to correct an error, see 1987 Amendment note below.

Pub. L. 100-360, §204(a)(1)(A), redesignated par. (14) as (15).

Subsec. (s)(16). Pub. L. 100-360, §411(i)(4)(C)(iii), amended directory language of Pub. L. 100-203, §4085(i)(11), to correct an error, see 1987 Amendment note below.

Subsec. (t). Pub. L. 100-360, §202(a)(2), designated existing provisions as par. (1), inserted “and paragraph (2)”, and added pars. (2) to (4) defining “covered outpatient drug” and “covered home IV drug”.

Subsec. (u). Pub. L. 100-360, §203(e)(1), inserted “home intravenous drug therapy provider,” after “hospice program,”.

Subsec. (v)(1)(G)(i). Pub. L. 100-360, §104(d)(4)(D), struck out “post-hospital” before “extended care services” in four places.

Subsec. (v)(1)(L)(iii). Pub. L. 100-360, §411(d)(5)(A), substituted “verified” for “audited” in subcls. (I) and (II) and inserted at end “In the case of a home health agency that refuses to provide data, or deliberately provides false data, respecting wages for purposes of this clause upon the request of the Secretary, the Secretary may withhold up to 5 percent of the amount of the payments otherwise payable to the agency under this subchapter until such date as the Secretary determines that such data has been satisfactorily provided.”

Subsec. (v)(2)(A), (3). Pub. L. 100-360, §104(d)(4)(D), struck out “post-hospital” before “extended care services”.

Subsec. (y). Pub. L. 100-360, §104(d)(4)(E)(i), substituted “Extended care” for “Post-hospital extended care” in heading.

Subsec. (y)(1). Pub. L. 100-360, §104(d)(4)(E)(ii), struck out “(except for purposes of subsection (a)(2))” after “Massachusetts, but only”.

Subsec. (y)(2). Pub. L. 100-360, §104(d)(4)(E)(i), (iii), (iv), struck out “post-hospital” before “extended care services” in two places, substituted “year” for “spell of illness” and “spell” wherever each appeared, and substituted “45 days” for “30 days”.

Subsec. (y)(3). Pub. L. 100-360, §104(d)(4)(E)(i), (iii), (v), struck out “post-hospital” before “extended care services” and substituted “year” for “spell of illness”, “the coinsurance amount established under section 1395e(a)(3)(C) of this title for each day before the 46th day” for “one-eighth of the inpatient hospital deductible for each day before the 31st day”, and “year” for “spell”.

Subsec. (y)(4). Pub. L. 100-360, §104(d)(4)(E)(vi), struck out par. (4) which provided that certain determinations about services provided by an institution described in par. (1) be made under regulations.

Subsec. (bb)(2). Pub. L. 100-360, §411(i)(3), added Pub. L. 100-203, §4084(c)(1), see 1987 Amendment note below.

Subsec. (ff). Pub. L. 100-360, §411(h)(1)(B)(i), inserted heading.

Subsec. (ff)(3). Pub. L. 100-360, §411(h)(1)(B)(ii), substituted “furnished by a hospital to its outpatients” for “hospital-based or hospital-affiliated (as defined by the Secretary)”.

Subsec. (gg). Pub. L. 100-360, §411(h)(4)(D), amended Pub. L. 100-203, §4073(c), see 1987 Amendment note below.

Subsec. (hh). Pub. L. 100-360, §411(h)(5)(B), amended Pub. L. 100-203, §4074(b), see 1987 Amendment note below.

Subsec. (ii). Pub. L. 100-647, §8423(a), inserted “on-site” before “at a community mental health center” and “, and such services that are necessarily furnished off-site (other than at an off-site office of such psychologist) as part of a treatment plan because of the inability of the individual furnished such services to travel to the center by reason of physical or mental impair-

ment, because of institutionalization, or because of similar circumstances of the individual,” after “Public Health Service Act”).

Pub. L. 100-360, § 411(h)(7)(E), (F), redesignated and amended Pub. L. 100-203, § 4077(b)(4), see 1987 Amendment note below.

Subsec. (jj). Pub. L. 100-485, § 608(d)(6)(A), inserted heading.

Pub. L. 100-360, § 203(b), added subsec. (jj) relating to home intravenous drug therapy services.

Subsec. (kk). Pub. L. 100-360, § 204(a)(2), added subsec. (kk) relating to screening mammography.

Subsec. (ll). Pub. L. 100-360, § 205(b), added subsec. (ll) relating to in-home care furnished to chronically dependent individual.

1987—Subsec. (a)(2). Pub. L. 100-203, § 4201(d)(1), formerly § 4201(d), as redesignated and amended by Pub. L. 100-360, § 411(f)(1)(B)(i), (ii), substituted “facility described in section 1395i-3(a)(1) of this title or subsection (y)(1)” for “skilled nursing facility”.

Subsec. (b)(3). Pub. L. 100-203, § 4009(e)(1), inserted “(including clinical psychologist (as defined by the Secretary))” before “under arrangements”.

Subsec. (b)(4). Pub. L. 100-203, § 4085(i)(9), substituted “and anesthesia” for “, anesthesia” and “certified registered nurse” for “certified certified registered nurse”.

Subsec. (b)(6). Pub. L. 100-203, § 4039(b)(2), substituted “Council on Podiatric Medical Education of the American Podiatric Medical Association” for “Council on Podiatry Education of the American Podiatry Association”.

Subsec. (e)(4). Pub. L. 100-203, § 4009(f), inserted “with respect to whom payment may be made under this subchapter” after “patient”.

Subsec. (g). Pub. L. 100-203, § 4085(i)(10), made technical amendment to heading.

Subsec. (j). Pub. L. 100-203, § 4201(a)(1), amended subsec. generally, substituting provision defining “skilled nursing facility” as having the meaning given such term in section 1395i-3(a) of this title for provision defining “skilled nursing facility” as, except for purposes of subsec. (a)(2) of this section, an institution or a distinct part of an institution which has in effect a transfer agreement, meeting the requirements of subsec. (l) of this section, with one or more hospitals having agreements in effect under section 1395cc of this title and which meet a specified list of criteria.

Subsec. (n). Pub. L. 100-203, § 4201(d)(2), (5), as added by Pub. L. 100-360, § 411(l)(1)(B)(iii), and Pub. L. 100-360, § 411(l)(1)(C), as added by Pub. L. 100-485, § 608(d)(27)(B), made similar amendments, resulting in the substitution of “subsection (e)(1) of this section or section 1395i-3(a)(1) of this title” for “subsection (e)(1) or (j)(1) of this section” in introductory provisions.

Subsec. (o)(6). Pub. L. 100-203, § 4021(a), inserted “the conditions of participation specified in section 1395bbb(a) of this title and” after “meets”.

Subsec. (r)(3). Pub. L. 100-203, § 4039(b)(1), substituted “subsections (k), (m), (p)(1), and (s) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title” for “subsection (s) of this section”, and struck out “; and for the purposes of subsections (k), (m), and (p)(1) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title but only if his performance of functions under subsections (k), (m), and (p)(1) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title is consistent with the policy of the institution or agency with respect to which he performs them and with the functions which he is legally authorized to perform”.

Subsec. (s). Pub. L. 100-203, § 4085(i)(11), substituted in closing provisions “which would not be included under subsection (b) if it were furnished to an inpatient of a hospital.” for “which—” before par. (15) and struck out pars. (15) and (16).

Pub. L. 100-203, § 4064(e)(1), inserted “a laboratory not independent of a physician’s office that has a volume of clinical diagnostic laboratory tests exceeding 5,000 per year” in provisions preceding par. (13).

Subsec. (s)(2)(B). Pub. L. 100-203, § 4070(b)(1), inserted “and partial hospitalization services incident to such services” before semicolon.

Subsec. (s)(2)(H)(ii). Pub. L. 100-203, § 4074(a), as amended by Pub. L. 100-360, § 411(h)(5)(A), inserted “or by a clinical social worker (as defined in subsection (hh))” after “clinical psychologist (as defined by the Secretary)”, and substituted “incident to such clinical psychologist’s services or clinical social worker’s services” for “incident to his services”.

Subsec. (s)(2)(J). Pub. L. 100-203, § 4075(a), substituted “prescription drugs used in immunosuppressive therapy” for “immunosuppressive drugs”.

Subsec. (s)(2)(K)(i). Pub. L. 100-203, § 4076(a), as amended by Pub. L. 100-360, § 411(h)(6), inserted “(I)” and substituted “, (II) as an assistant at surgery, or (III) in a rural area (as defined in section 1395ww(d)(2)(D) of this title) that is designated, under section 332(a)(1)(A) of the Public Health Service Act, as a health manpower shortage area,” for “or as an assistant at surgery”.

Subsec. (s)(2)(L). Pub. L. 100-203, § 4073(a), added subpar. (L).

Subsec. (s)(2)(M). Pub. L. 100-203, § 4077(b)(1), as amended by Pub. L. 100-360, § 411(h)(7)(A), added subpar. (M).

Subsec. (s)(10)(A). Pub. L. 100-203, § 4071(a), inserted “and influenza vaccine and its administration” before semicolon.

Subsec. (s)(12). Pub. L. 100-203, § 4072(a), added par. (12). Former par. (12) redesignated (13).

Subsec. (s)(13), (14). Pub. L. 100-203, § 4072(a)(1), redesignated pars. (12) and (13) as (13) and (14), respectively. Former par. (14) redesignated (15).

Subsec. (s)(15). Pub. L. 100-203, § 4085(i)(11), as amended by Pub. L. 100-360, § 411(i)(4)(C)(iii), struck out par. (15) which read as follows: “would not be included under subsection (b) of this section if it were furnished to an inpatient of a hospital; or”.

Pub. L. 100-203, § 4072(a)(1), redesignated par. (14) as (15). Former par. (15) redesignated (16).

Subsec. (s)(16). Pub. L. 100-203, § 4085(i)(11), as amended by Pub. L. 100-360, § 411(i)(4)(C)(iii), struck out par. (16) which read as follows: “is furnished under arrangements referred to in such paragraph (2)(C) unless furnished in the hospital or in other facilities operated by or under the supervision of the hospital or its organized medical staff.”

Pub. L. 100-203, § 4072(a)(1), redesignated par. (15) as (16).

Subsec. (v)(1)(E). Pub. L. 100-203, § 4201(b)(1), inserted at end “Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1395i-3 of this title (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).”

Subsec. (v)(1)(L)(iii). Pub. L. 100-203, § 4026(a)(1), added cl. (iii).

Subsec. (v)(1)(S). Pub. L. 100-203, § 4065(a), added subpar. (S).

Subsec. (v)(5)(A). Pub. L. 100-203, § 4085(i)(12), made technical amendments to references in original act which appear in text as references to “subsection (p)” and “subsection (g)”.

Subsec. (aa)(1)(B). Pub. L. 100-203, § 4077(a)(1), substituted “physician assistant or a nurse practitioner (as defined in paragraph (3)), or by a clinical psychologist (as defined by the Secretary),” for “physician assistant or by a nurse practitioner”.

Subsec. (bb). Pub. L. 100-203, § 4085(i)(13), made technical amendment to heading.

Subsec. (bb)(2). Pub. L. 100-203, § 4084(c)(1), as added by Pub. L. 100-360, § 411(i)(3), inserted at end “Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.”

Subsec. (cc)(1). Pub. L. 100-203, § 4078, inserted provision at end relating to location requirements in case of physical therapy, occupational therapy, and speech pathology services.

Subsec. (ee). Pub. L. 100-203, §4085(i)(14), made technical amendment to heading.

Subsec. (ff). Pub. L. 100-203, §4070(b)(2), added subsec. (ff).

Subsec. (gg). Pub. L. 100-203, §4073(c), as amended by Pub. L. 100-360, §411(h)(4)(D), added subsec. (gg).

Subsec. (hh). Pub. L. 100-203, §4074(b), as amended by Pub. L. 100-360, §411(h)(5)(B), added subsec. (hh).

Subsec. (ii). Pub. L. 100-203, §4077(b)(4), formerly §4077(b)(5), as redesignated and amended by Pub. L. 100-360, §411(h)(7)(E), (F), added subsec. (ii).

1986—Subsec. (b)(4). Pub. L. 99-509, §9320(f), inserted before the semicolon at end “, anesthesia services provided by a certified registered nurse anesthetist”.

Subsec. (e)(6). Pub. L. 99-509, §9305(c)(1), inserted “(A)” after “(6)” and cl. (B).

Subsec. (g). Pub. L. 99-509, §9337(d)(1), added subsec. (g).

Subsec. (n). Pub. L. 99-272, §9219(b)(1)(B), substituted “as his home” for “at his home”.

Subsec. (r)(4). Pub. L. 99-509, §9336(a), amended cl. (4) generally. Prior to amendment, cl. (4) read as follows: “a doctor of optometry who is legally authorized to practice optometry by the State in which he performs such function, but only with respect to services related to the condition of aphakia, or”.

Subsec. (s)(2)(D). Pub. L. 99-509, §9337(d)(2), inserted “and outpatient occupational therapy services”.

Subsec. (s)(2)(J). Pub. L. 99-509, §9335(c)(1), added subpar. (J).

Subsec. (s)(2)(K). Pub. L. 99-509, §9338(a), added subpar. (K).

Subsec. (s)(11) to (15). Pub. L. 99-509, §9320(b), added par. (11) and redesignated former pars. (11) to (14) as (12) to (15), respectively.

Subsec. (v)(1)(B). Pub. L. 99-272, §9107(b)(2), substituted “any cost reporting period shall be equal to” for “any fiscal period shall not exceed one and one-half times” and “the period” for “such fiscal period”.

Subsec. (v)(1)(G)(i). Pub. L. 99-272, §9219(b)(3)(A), inserted “on the basis of” after “(during such period)” in provisions following subcl. (III).

Subsec. (v)(1)(L). Pub. L. 99-509, §9315(a), inserted “(i)” after “(L)”, struck out “the 75th percentile of such costs per visit for free standing home health agencies, or, in the judgment of the Secretary, such lower percentile or such comparable or lower limit (based on or related to the mean of the costs of such agencies or otherwise) as the Secretary may determine.”, and substituted in lieu “for cost reporting periods beginning on or after—

“(I) July 1, 1985, and before July 1, 1986, 120 percent,

“(II) July 1, 1986, and before July 1, 1987, 115 percent, or

“(III) July 1, 1987, 112 percent,

of the mean of the labor-related and nonlabor per visit costs for free standing home health agencies.

“(i) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis, with appropriate adjustment for administrative and general costs of hospital-based agencies.”

Subsec. (v)(1)(O)(i). Pub. L. 99-272, §9110(a)(1), inserted “, except as provided in clause (iv),” after “such regulations shall provide”.

Subsec. (v)(1)(O)(iv). Pub. L. 99-272, §9110(a)(2), added cl. (iv).

Subsec. (v)(1)(P). Pub. L. 99-272, §9107(b)(1), added subpar. (P).

Subsec. (v)(1)(Q). Pub. L. 99-272, §9202(i)(1), added subpar. (Q).

Subsec. (v)(1)(R). Pub. L. 99-509, §9313(a)(2), added subpar. (R).

Subsec. (v)(5)(A). Pub. L. 99-509, §9337(d)(3), inserted “(including through the operation of subsection (g))” after “subsection (p)”.

Subsec. (bb). Pub. L. 99-509, §9320(c), added subsec. (bb).

Subsec. (ee). Pub. L. 99-509, §9305(c)(2), added subsec. (ee).

1984—Subsec. (d). Pub. L. 98-369, §2335(b)(1), struck out subsec. (d) which defined “inpatient tuberculosis hospital services” as inpatient hospital services furnished to an inpatient of a tuberculosis hospital.

Subsec. (e). Pub. L. 98-369, §2335(b)(2), struck out “or tuberculosis unless it is a tuberculosis hospital (as defined in subsection (g) of this section) or” before “unless it is a psychiatric hospital” in provisions following par. (9).

Subsec. (f). Pub. L. 98-369, §2340(a), struck out par. (5) which provided that “psychiatric hospital” meant an institution which was accredited by the Joint Commission on Accreditation of Hospitals, and struck out “if the institution is accredited by the Joint Commission on Accreditation of Hospitals or if such distinct part meets requirements equivalent to such accreditation requirements as determined by the Secretary” in concluding provisions.

Subsec. (g). Pub. L. 98-369, §2335(b)(1), struck out subsec. (g) which defined “tuberculosis hospital”.

Subsec. (j). Pub. L. 98-369, §2335(b)(3), in provisions following par. (15), struck out “or tuberculosis” after “treatment of mental diseases”.

Subsec. (j)(2). Pub. L. 98-369, §2354(b)(18), substituted “provision for” for “provision of”.

Subsec. (j)(13). Pub. L. 98-369, §2354(b)(19), substituted “an institution” for “a nursing home”.

Subsec. (m)(5). Pub. L. 98-369, §2321(e)(1), which directed the substitution of “and durable medical equipment” for “, and the use of medical appliances” was executed by making the substitution for “, and the use of medical appliances” as the probable intent of Congress.

Subsec. (n). Pub. L. 98-369, §2321(e)(3), added subsec. (n).

Subsec. (p)(1). Pub. L. 98-369, §2341(a), substituted “paragraph (1) or (3) of subsection (r)” for “subsection (r)(1)”.

Subsec. (p)(2). Pub. L. 98-369, §2342(a), substituted “by a physician as so defined) or by a qualified physical therapist and is periodically reviewed by a physician (as so defined)” for “, and is periodically reviewed, by a physician (as so defined)”.

Subsec. (r)(3). Pub. L. 98-617, §3(b)(7), substituted “under subsections (k), (m), and (p)(1) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title” for “under subsections (k) and (m) and sections 1395f(a) and 1395n of this title” before “is consistent with the policy”.

Pub. L. 98-369, §2341(c), substituted “for the purposes of subsections (k), (m), and (p)(1) of this section” for “for the purposes of subsections (k) and (m) of this section”, and substituted “sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title but only if” for “sections 1395f(a) and 1395n of this title but only if”.

Subsec. (s)(2)(H). Pub. L. 98-369, §2322(a), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (s)(2)(I). Pub. L. 98-369, §2324(a), added subpar. (I).

Subsec. (s)(6). Pub. L. 98-369, §2321(e)(2), struck out provision which included iron lungs, oxygen tents, etc. with durable medical equipment. See subsec. (n) of this section.

Subsec. (s)(10). Pub. L. 98-369, §2323(a), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (u). Pub. L. 98-369, §2354(b)(20), struck out “or” before “home health agency”.

Subsec. (v)(1)(B). Pub. L. 98-369, §2354(b)(21)(A), realigned margin of subpar. (B).

Subsec. (v)(1)(C). Pub. L. 98-369, §2354(b)(21)(B), realigned margins of subpar. (C).

Subsec. (v)(1)(C)(i). Pub. L. 98-369, §2354(b)(22), inserted a dash after “but only if”.

Subsec. (v)(1)(D). Pub. L. 98-369, §2354(b)(21)(B), realigned margin of subpar. (D).

Pub. L. 98-369, §2354(b)(21)(C), inserted a comma after “section 1395k(a)(2)(B)(i) of this title”.

Subsec. (v)(1)(E). Pub. L. 98-369, §2319(a)(1), struck out cl. (i) which directed that such regulations provide that any determination of reasonable cost with respect

to services provided by hospital-based skilled nursing facilities be made on the basis of a single standard based on the reasonableness of costs incurred by free standing skilled nursing facilities, subject to such adjustments as deemed appropriate by the Secretary, and struck out the designation "(ii)".

Pub. L. 98-369, § 2354(b)(23), as amended by Pub. L. 98-617, § 3(a)(4), substituted "use" for "uses".

Subsec. (v)(1)(I)(i), (ii). Pub. L. 98-369, § 2354(b)(24), substituted "by the Secretary, or upon request by the Comptroller General" for "to the Secretary, or upon request to the Comptroller General".

Subsec. (v)(1)(K). Pub. L. 98-369, § 2318(a), (b), designated existing provisions as cl. (i), substituted therein "as defined in clause (ii)" for "provided in an emergency room", and added cl. (ii).

Subsec. (v)(1)(O). Pub. L. 98-369, § 2314(a), added subpar. (O).

Subsec. (v)(3). Pub. L. 98-369, § 2354(b)(25), substituted "semi-private" for "semiprivate" after "furnished in".

Subsec. (v)(7)(D). Pub. L. 98-369, § 2319(a)(2), added subpar. (D).

Subsec. (z)(2). Pub. L. 98-369, § 2354(b)(26), substituted "paragraph (1)" for "subparagraph (1)".

Subsec. (aa)(2)(I). Pub. L. 98-369, § 2354(b)(27), substituted "utilization" for "ultilization".

Subsec. (cc)(1)(F). Pub. L. 98-369, § 2354(b)(28), substituted "self-administered" for "self administered".

Subsec. (cc)(1)(G). Pub. L. 98-369, § 2321(e)(4), substituted "and durable medical equipment" for "appliances, and equipment, including the purchase or rental of equipment".

Subsec. (cc)(2)(F). Pub. L. 98-369, § 2354(b)(29), substituted "standards established" for "standard establishment".

Subsec. (dd)(2)(A)(ii)(I). Pub. L. 98-369, § 2343(a), inserted "except as otherwise provided in paragraph (5)".

Subsec. (dd)(5). Pub. L. 98-369, § 2343(b), added par. (5). 1983—Subsec. (v)(1)(G)(i). Pub. L. 98-21, § 602(d)(1), substituted "the amount otherwise payable under part A with respect to" for "on the basis of the reasonable cost of" in provisions following subcl. (III).

Subsec. (v)(2)(A). Pub. L. 98-21, § 602(d)(2), substituted "the amount that would be taken into account with respect to" for "an amount equal to the reasonable cost of".

Subsec. (v)(2)(B). Pub. L. 98-21, § 602(d)(3), struck out "the equivalent of the reasonable cost of" after "only".

Subsec. (v)(3). Pub. L. 98-21, § 602(d)(4), substituted "the amount otherwise payable under this subchapter for such bed and board furnished in semiprivate accommodations" for "the reasonable cost of such bed and board furnished in semiprivate accommodations (determined pursuant to paragraph (1))".

Subsec. (v)(7)(C). Pub. L. 97-448 amended directory language of Pub. L. 97-248, § 109(b)(2), to correct typographical error, and did not involve any change in text. See 1982 Amendment note below.

Subsec. (z)(2). Pub. L. 98-21, § 607(d), designated existing provisions as subpar. (A) and added subpar. (B).

Pub. L. 98-21, § 607(b)(2), substituted "\$600,000 (or such lesser amount as may be established by the State under section 1320a-1(g)(1) of this title in which the hospital is located)" for "\$100,000".

1982—Subsec. (e)(C). Pub. L. 97-248, § 128(d)(2), substituted "(i) may" for "may (i)".

Subsec. (s)(2)(H). Pub. L. 97-248, § 114(b), added subpar. (H).

Subsec. (u). Pub. L. 97-248, § 122(d)(1), inserted "hospice program," after "home health agency,".

Subsec. (v)(1)(E). Pub. L. 97-248, § 102(a), struck out provisions that this subparagraph would not apply to any skilled nursing facility that either was a distinct part of or directly operated by a hospital or was in a close, formal satellite relationship with a participating hospital, and in the case of the latter, the reasonable cost of any services furnished by such facility as determined by the Secretary under this subsection would not exceed 150 percent of the costs determined by the application of this subparagraph, redesignated the remainder as cl. (ii), and added cl. (i).

Subsec. (v)(1)(G)(i). Pub. L. 97-248, § 148(b), substituted "quality control and peer review organization" for "Professional Standards Review Organization".

Subsec. (v)(1)(H)(iii). Pub. L. 97-248, § 109(b)(1), struck out "(I)" and "or (II) which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency".

Subsec. (v)(1)(I). Pub. L. 97-248, § 127(1), amended directory language of Pub. L. 96-499, § 952, by inserting "(a)" after "952", and did not involve any change in text. See 1980 Amendment note below.

Subsec. (v)(1)(J). Pub. L. 97-248, § 103(a), substituted provisions that cost regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities for provisions that such regulations would provide that an inpatient routine nursing salary cost differential would be allowable as a reimbursable cost of hospitals, at a rate not to exceed 5 percent, to be applied under the same methodology used for the nursing salary cost differential for the month of April 1981.

Subsec. (v)(1)(L). Pub. L. 97-248, § 101(a)(2), struck out cl. (i) which provided that the Secretary, in determining the amount of the payments that could be made under this subchapter with respect to routine operating costs for the provision of general inpatient hospital services, could not recognize as reasonable, routine operating costs for the provision of general inpatient hospital services by a hospital to the extent these costs exceeded 108 percent of the mean of such routine operating costs per diem for hospitals, or, in the judgment of the Secretary, such lower percentage or such comparable or lower limit as the Secretary could determine, and struck out "(ii)".

Pub. L. 97-248, § 105(a), inserted "free standing" after "costs per visit for".

Subsec. (v)(1)(M). Pub. L. 97-248, § 106(a), added subpar. (M).

Subsec. (v)(1)(N). Pub. L. 97-248, § 107(a), added subpar. (N).

Subsec. (v)(7). Pub. L. 97-248, § 101(d), redesignated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (v)(7)(C). Pub. L. 97-248, § 108(a)(2), added subpar. (C).

Pub. L. 97-248, § 109(b)(2), as amended by Pub. L. 97-448, § 309(a)(4), inserted "and for payments under certain percentage arrangements".

Subsec. (w)(1). Pub. L. 97-248, § 122(d)(2), substituted "home health agency, or hospice program" for "or home health agency".

Subsec. (w)(2). Pub. L. 97-248, § 148(b), substituted "quality control and peer review organization" for "Professional Standards Review Organization".

Subsec. (cc)(1). Pub. L. 97-248, § 128(a)(1), substituted "inpatient" for "outpatient" in provisions following subpar. (H).

Subsec. (dd). Pub. L. 97-248, § 122(d)(3), added subsec. (dd).

1981—Subsec. (u). Pub. L. 97-35, § 2121(c), struck out "detoxification facility," after "home health agency,".

Subsec. (v)(1)(G)(i). Pub. L. 97-35, § 2102(a)(1), substituted "there is not an excess of hospital beds in such hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital" for "the hospital had (during the immediately preceding calendar year) an average daily occupancy rate of 80 percent or more" in provision following subcl. (III).

Pub. L. 97-35, § 2114, substituted "the Secretary or such agent as the Secretary may designate" for "an organization or agency with review responsibility as is otherwise provided for under part A of subchapter XI of this chapter" in provision preceding subcl. (I).

Subsec. (v)(1)(G)(iv). Pub. L. 97-35, § 2102(a)(2), substituted provisions that the determination under cl. (i) of this subparagraph, in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, be made on the basis of only the public hospitals which are in the area of the hospital and which are under common ownership with that hos-

pital for provisions that public hospitals under common ownership may elect to be treated as a single hospital, and beginning two years after the date this subparagraph is first applied with respect to a hospital, the Secretary, to the extent feasible, shall not treat as an inpatient an individual with respect to whom payment was made to the hospital only because of this subparagraph or section 1396a(h) of this title for such determination.

Subsec. (v)(1)(J). Pub. L. 97-35, §2141(a), added subpar. (J).

Subsec. (v)(1)(K). Pub. L. 97-35, §2142(a), added subpar. (K).

Subsec. (v)(1)(L). Pub. L. 97-35, §2143(a), added subpar. (L).

Pub. L. 97-35, §2144(a), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (w)(2). Pub. L. 97-35, §2193(c)(9), substituted "subchapter XIX" for "subchapter V or XIX".

Subsec. (bb). Pub. L. 97-35, §2121(d), struck out subsec. (bb) which defined "alcohol detoxification facility services" and "detoxification facility".

1980—Subsec. (b)(7). Pub. L. 96-499, §948(a)(1), provided that par. (4) was not to apply to services provided in a hospital by a physician where the hospital had a teaching program approved as specified in par. (6) if the hospital elected to receive payment for reasonable costs of such services and all physicians in such hospital agreed not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this subchapter.

Subsec. (e). Pub. L. 96-499, §930(k), substituted "subsection (i)" for "subsections (i) and (n)" in text preceding par. (1) and in text following par. (9).

Pub. L. 96-499, §949, in text following par. (9), inserted provision defining "hospital" as a facility of fifty beds or less located in an area determined by the Secretary to meet definition relating to a rural area described in subpar. (A) of par. (5) and prescribing exceptions to such definition.

Subsec. (i). Pub. L. 96-499, §950, substituted "30 days" for "14 days" in three places and struck out former cl. (B) which related to admission to skilled nursing facilities within 28 days after hospital discharge of an individual unable to be admitted to such facilities within 14 days because of a shortage of appropriate bed space, and redesignated former cl. (C) as (B).

Subsec. (j)(13). Pub. L. 96-499, §915(a), substituted "such edition (as is specified by the Secretary in regulations) of the Life Safety Code of the National Fire Protection Association" for "the Life Safety Code of the National Fire Protection Association (23rd edition, 1973)".

Subsec. (k)(2)(A). Pub. L. 96-499, §951(b), inserted "(of which at least two must be physicians described in subsection (r)(1) of this section)" after "two or more physicians".

Subsec. (m)(4). Pub. L. 96-499, §930(l), inserted "who has successfully completed a training program approved by the Secretary" after "health aide".

Subsec. (n). Pub. L. 96-499, §930(m), struck out subsec. (n) which defined "post-hospital home health services".

Subsec. (o). Pub. L. 96-499, §930(n)(2), in provisions following par. (7), struck out provision that "home health agency" was not to include a private organization which was not a nonprofit organization exempt from Federal income taxation under section 501 of title 26 unless it were licensed pursuant to State law and met such additional standards and requirements as prescribed by regulations.

Subsec. (o)(7). Pub. L. 96-499, §930(n)(1), added par. (7).

Subsec. (r)(2). Pub. L. 96-499, §936(a), amended cl. (2) generally to expand definition of "physician" to include doctors of dental surgery or dental medicine acting within the scope of their licenses.

Subsec. (r)(3). Pub. L. 96-499, §951(a), substituted provisions relating to doctors of podiatric medicine for provisions relating to doctors of podiatry and surgical chiropody.

Subsec. (r)(4). Pub. L. 96-499, §937(a), substituted "services related to the condition of aphakia" for "establishing the necessity for prosthetic lenses".

Subsec. (s)(2)(G). Pub. L. 96-499, §938(a), added subpar. (G).

Subsec. (s)(10) to (14). Pub. L. 96-611, §1(a)(1), added par. (10) and redesignated former pars. (10) to (13) as (11) to (14), respectively.

Subsec. (u). Pub. L. 96-499, §933(c), inserted "comprehensive outpatient rehabilitation facility," after "nursing facility".

Pub. L. 96-499, §931(c), inserted "detoxification facility,".

Subsec. (v)(1)(G). Pub. L. 96-499, §902(a)(1), added subpar. (G).

Subsec. (v)(1)(H). Pub. L. 96-499, §930(p), added subpar. (H).

Subsec. (v)(1)(I). Pub. L. 96-499, §952(a), formerly §952, as redesignated by Pub. L. 97-248, §127(1), added subpar. (I).

Subsec. (z). Pub. L. 96-499, §933(d), which purported to substitute "skilled nursing facility, comprehensive outpatient rehabilitation facility," for "extended care facility," was executed by inserting "comprehensive outpatient rehabilitation facility," after "skilled nursing facility," as the probable intent of Congress, in view of the substitution of "skilled nursing facility" for "extended care facility" by section 278(b)(6) of Pub. L. 92-603.

Subsec. (aa)(1)(A). Pub. L. 96-611, §1(b)(3), inserted reference to items and services described in subsection (s)(10) of this section.

Subsec. (bb). Pub. L. 96-499, §931(d), added subsec. (bb).

Subsec. (cc). Pub. L. 96-499, §933(e), added subsec. (cc). 1978—Subsec. (s)(2)(F). Pub. L. 95-292 added subpar. (F).

1977—Subsec. (j)(11). Pub. L. 95-142, §3(a)(2), substituted provisions relating to compliance with requirements of section 1320a-3 of this title, for provisions relating disclosure of ownership, corporate status, etc., information to the Secretary or his delegate.

Subsec. (j)(13). Pub. L. 95-142, §21(a), struck out "and" after "nursing facilities".

Subsec. (j)(14). Pub. L. 95-142, §21(a), added par. (14).

Subsec. (s). Pub. L. 95-210, §1(g), (h), added subpar. (E) of par. (2) and in provisions following par. (9) inserted "a rural health clinic," after "independent of a physician's office".

Subsec. (s)(6). Pub. L. 95-216 inserted "(which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe)" after "wheelchairs".

Subsec. (v)(1)(F). Pub. L. 95-142, §19(b)(1), added subpar. (F).

Subsec. (w)(2). Pub. L. 95-142, §5(m), inserted "part B of this subchapter or under" after "or entitled to have payment made for such services under".

Subsec. (aa). Pub. L. 95-210, §1(d), added subsec. (aa). 1975—Subsec. (e)(5). Pub. L. 94-182, §102, substituted "January 1, 1979" for "January 1, 1976".

Subsec. (j)(13). Pub. L. 94-182, §106(a), substituted "23d edition, 1973" for "21st edition, 1967".

Subsec. (w). Pub. L. 94-182, §112(a)(1), designated existing provisions as par. (1) and added par. (2).

1972—Subsec. (a)(2). Pub. L. 92-603, §278(a)(4), substituted "skilled nursing facility" for "extended care facility" and "a" for "an".

Subsec. (b)(6). Pub. L. 92-603, §§227(a), 276(a), redesignated existing second sentence of subsec. (b) as par. (6) and in subsec. (b)(6) as so designated inserted reference to services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatry Education of the American Podiatry Association.

Subsec. (b)(7). Pub. L. 92-603, §227(a), added par. (7).

Subsec. (e). Pub. L. 92-603, §211(b), inserted reference to section 1395f(f) of this title in the provisions preceding par. (1), inserted reference to sections 1395f(f)(2) of

this title after “For purposes of sections 1395f(d) and 1395n(b) of this title (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections),” and inserted provisions for accreditation by the Joint Commission on Accreditation of Hospitals.

Subsec. (e)(8). Pub. L. 92-603, § 234(a), added par. (8). Former par. (8) redesignated (9).

Subsec. (e)(9). Pub. L. 92-603, §§ 234(a), 244(c), redesignated former par. (8) as (9) and struck out provisions requiring that other requirements not be higher than the comparable requirements prescribed for the accreditation of hospitals by the Joint Commission on Accreditation of Hospitals.

Subsecs. (f)(2), (g)(2). Pub. L. 92-603, § 234(b), (c), inserted reference to par. (9) of subsec. (e) of this section.

Subsec. (h). Pub. L. 92-603, § 278(a)(5), substituted “skilled nursing facility” for “extended care facility”, “skilled nursing facilities” for “extended care facilities” and “a” for “an”.

Subsec. (i). Pub. L. 92-603, §§ 248, 278(a)(6), (b)(10), extended the class of persons qualifying to be deemed as having been an inpatient in a hospital immediately before transfer therefrom by designating as clause (A) the existing requirement that the person have been admitted to the skilled nursing facility within 14 days after discharge from such hospital and adding cls. (B) and (C) and substituted “skilled nursing facility” for “extended care facility”.

Subsec. (j). Pub. L. 92-603, § 278(a)(7), substituted “skilled nursing facility” for “extended care facility” in provisions preceding par. (1).

Subsec. (j)(10). Pub. L. 92-603, § 234(d), added par. (10). Former par. (10) redesignated par. (11) by section 234(d)(2) of Pub. L. 92-603 and again redesignated par. (15) by section 246(b)(2) of Pub. L. 92-603.

Subsec. (j)(11) to (13). Pub. L. 92-603, § 246(b)(3), added pars. (11) to (13).

Subsec. (j)(15). Pub. L. 92-603, §§ 234(d), 246(b)(2), (4), 265, 267, 278(b)(13), redesignated former par. (10) as (11), amended par. (11) as thus redesignated by inserting provisions that the Secretary shall not require as a condition of participation that medical social services be furnished in any such institution, redesignated such par. (11) as thus amended as par. (15), and inserted provision that all information concerning skilled nursing facilities required to be filed with the Secretary be made available to Federal and state employees for purposes consistent with the effective administration of programs established under subchapters XVIII and XIX and inserted provision for the waiver of the registered nurse requirement in skilled nursing facilities in rural areas.

Subsec. (k). Pub. L. 92-603, §§ 237(c), 278(a)(8), inserted provisions authorizing the Secretary to utilize the procedures established under subchapter XIX of this chapter if such procedures were determined to be superior in their effectiveness and substituted “skilled nursing facility” for “extended care facility”, “skilled nursing facilities” for “extended care facilities”, and “a” for “an”.

Subsec. (l). Pub. L. 92-603, § 278(a)(9), substituted “skilled nursing facility” for “extended care facility” and “a” for “an”.

Subsec. (m)(7). Pub. L. 92-603, § 278(a)(10), substituted “skilled nursing facility” for “extended care facility”.

Subsec. (n). Pub. L. 92-603, § 278(a)(11), substituted “skilled nursing facility” for “extended care facility” and “a” for “an”.

Subsec. (o)(5), (6). Pub. L. 92-603, § 234(e), added par. (5) and redesignated former par. (5) as (6).

Subsec. (p). Pub. L. 92-603, §§ 251(a)(1), (b)(1), 283(a), inserted provisions covering physical therapy services of a licensed physical therapist other than under an arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency, inserted “In addition, such term includes physical therapy services which meet the requirements of the first sentence of this subsection except that they are furnished to an individual as an in-

patient of a hospital or extended care facility”, and extended definition of “outpatient physical therapy services” to include outpatient speech pathology services.

Subsec. (q). Pub. L. 92-603, § 227(f), substituted “subsection (b)(6)” for “the last sentence of subsection (b)” in parenthetical phrase.

Subsec. (r). Pub. L. 92-603, §§ 211(c)(2), 256(b), 264(a), 273(a), inserted “or (C) the certification required by section 1395x(a)(2)(E) of this title,” inserted provision so as to include doctors in one of the specified arts legally authorized to practice such art in the country in which inpatient hospital services referred to in section 1395y(a)(4) are furnished, added cl. (4) covering doctors of optometry who are legally authorized to practice optometry by the State in which they perform such functions, but only with respect to establishing the necessity for prosthetic lenses, and added cl. (5) providing for the inclusion of chiropractor services.

Subsec. (s)(8). Pub. L. 92-603, § 252(a), inserted “(including colostomy bags and supplies directly related to colostomy care)” after “organ”.

Subsec. (u). Pub. L. 92-603, §§ 227(d)(1), 278(a)(12), substituted “skilled nursing facility, or home health agency, or, for purposes of sections 1395(g) and 1395n(e) of this title, a fund.” for “extended care facility, or home health agency.”.

Subsec. (v)(1). Pub. L. 92-603, §§ 223(a), (b), (c), (d), 227(c)(1), (2), (3), (4), 249(b), 278(b)(11), inserted definition of the costs of services, inserted provision that the regulation for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as reasonable based on estimates of the costs necessary in the efficient delivery of needed health services to individuals covered by the insurance programs established under this subchapter, inserted parenthetical provisions covering exclusion of costs, substituted “the necessary costs of efficiently delivering covered services covered by the insurance programs” for “the costs with respect to individuals covered by the insurance programs”, designated existing provisions as subpars. (A) and (B), and added subpars. (C), (D), and (E), and substituted “skilled nursing facilities” for “extended care facilities”.

Subsec. (v)(3). Pub. L. 92-603, § 278(a)(13), substituted “skilled nursing facility” for “extended care facility”.

Subsec. (v)(4). Pub. L. 92-603, § 223(f), added par. (4). Former par. (4) redesignated (6).

Subsec. (v)(5). Pub. L. 92-603, § 251(c), added par. (5).

Subsec. (v)(6). Pub. L. 92-603, §§ 223(f), 251(c), redesignated former par. (4) as (6).

Subsec. (v)(7). Pub. L. 92-603, §§ 221(c)(4), 223(b), 251(c), added par. (7).

Subsecs. (w), (y). Pub. L. 92-603, § 278(a)(14), (15), substituted “skilled nursing facility” for “extended care facility” and “a” for “an”.

Subsec. (z). Pub. L. 92-603, §§ 234(b), 278(b)(6), added subsec. (z) and substituted “skilled nursing facility” for “extended care facility”.

1971—Subsec. (e)(5). Pub. L. 91-690 authorized the Secretary, until January 1, 1976, to waive the requirement relating to the provision of 24 hour nursing service rendered or supervised by a registered professional nurse.

1968—Subsec. (e). Pub. L. 90-248, § 129(c)(9)(C), inserted reference to section 1395n(b) in first and third sentences and inserted “or diagnostic services” after “hospital services” in third sentence.

Pub. L. 90-248, § 143(a), in second sentence after par. (8), changed definition of hospitals for purposes of making payments for emergency hospital services by deleting provision that hospital meet requirements of pars. (1) to (4), by requiring that such hospitals have full-time nursing services, be licensed as a hospital, and be primarily engaged in providing not nursing care and related services but medical or rehabilitative care by or under the supervision of a doctor of medicine or osteopathy.

Subsec. (p). Pub. L. 90-248, §§ 129(c)(10), 133(b), struck out definition of “outpatient hospital diagnostic services” and inserted definition of “outpatient physical therapy services”, respectively.

Subsec. (r)(3). Pub. L. 90-248, §127(a), added cl. (3).

Subsec. (s). Pub. L. 90-248, §144(a)-(c), struck out “(unless they would otherwise constitute inpatient hospital services, extended care services, or home health services)” after “items or services” in text preceding par. (1), inserted after “hospital” in sentence following par. (9) “which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title”, and inserted sentence following par. (13) providing that medical and other health services (other than physicians’ services and services incident to physicians’ services) furnished a patient of a facility which meets the definition of a hospital for emergency services will be covered under the medical insurance program only if such facility satisfies such health and safety requirements as are appropriate for the item or service furnished as the Secretary may determine are necessary.

Subsec. (s)(2)(A) to (C). Pub. L. 90-248, §129(a), designated existing provisions as subpars. (A) and (B) and added subpar. (C).

Subsec. (s)(2)(D). Pub. L. 90-248, §133(a), added subpar. (D).

Subsec. (s)(3). Pub. L. 90-248, §134(a), included in medical and other health services diagnostic X-ray tests furnished in the patient’s home under the supervision of a physician if the tests meet such health and safety conditions as the Secretary finds necessary.

Subsec. (s)(6). Pub. L. 90-248, §132(a), provided that payments may be made with respect to expenses incurred in the purchase as well as in the rental of durable medical equipment.

Pub. L. 90-248, §144(d), inserted “other than in institution that meets the requirements of subsection (e)(1) or (j)(1) of this section”.

Subsec. (s)(12), (13). Pub. L. 90-248, §129(b), added pars. (12) and (13) which excluded from the diagnostic services referred to in par. (2)(C) (other than physician’s services) certain items or service.

Subsec. (y)(3). Pub. L. 90-248, §129(c)(11), substituted “1395e(a)(3)” for “1395e(a)(4)”.

1966—Subsec. (v)(1). Pub. L. 89-713 inserted provisions which required that, in the case of extended care services furnished by proprietary facilities, the regulations include provision for specific recognition of a reasonable return on equity capital and which placed a limitation on the rate of return of one and one-half times the average of the rates of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108-173, set out as a note under section 1395w-21 of this title.

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115-271, title II, §2002(d), Oct. 24, 2018, 132 Stat. 3926, provided that: “The amendments made by this section [amending this section] shall apply to examinations and visits furnished on or after January 1, 2020.”

Amendment by section 51006(a)(1) of Pub. L. 115-123 applicable to items and services furnished on or after Jan. 1, 2019, see section 51006(b) of Pub. L. 115-123, set out as a note under section 1395f of this title.

Pub. L. 115-123, div. E, title X, §51008(c), Feb. 9, 2018, 132 Stat. 297, provided that: “The amendments made by this section [amending this section] shall apply to items and services furnished on or after January 1, 2024.”

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114-255 applicable to items and services furnished on or after Jan. 1, 2021, see section 5012(d) of Pub. L. 114-255, set out as a note under section 1395l of this title.

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114-113 applicable to items furnished on or after Jan. 1, 2017, see section 504(d) of Pub. L. 114-113, set out as a note under section 1395l of this title.

Pub. L. 114-40, §2(b), July 30, 2015, 129 Stat. 441, provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to devices furnished on or after January 1, 2016.”

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112-40 applicable to contracts entered into or renewed on or after Jan. 1, 2012, see section 261(e) of Pub. L. 112-40, set out as a note under section 1320c of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111-152, title I, §1301(c), Mar. 30, 2010, 124 Stat. 1057, provided that: “The amendments made by this section [amending this section] shall apply to items and services furnished on or after the first day of the first calendar quarter that begins at least 12 months after the date of the enactment of this Act [Mar. 30, 2010].”

Amendment by section 4103(a), (b) of Pub. L. 111-148 applicable to services furnished on or after Jan. 1, 2011, see section 4103(e) of Pub. L. 111-148, set out as a note under section 1395l of this title.

Amendment by section 4104(a) of Pub. L. 111-148 applicable to items and services furnished on or after Jan. 1, 2011, see section 4104(d) of Pub. L. 111-148, set out as a note under section 1395l of this title.

Pub. L. 111-148, title V, §5502(a)(2), Mar. 23, 2010, 124 Stat. 654, which provided that the amendment made by section 5502(a)(1) (amending this section) applied to services furnished on or after Jan. 1, 2011, was repealed by Pub. L. 111-148, title X, §10501(i)(1), Mar. 23, 2010, 124 Stat. 997.

Pub. L. 111-148, title X, §10501(i)(2)(B), Mar. 23, 2010, 124 Stat. 997, provided that: “The amendment made by subparagraph (A) [amending this section] shall apply to services furnished on or after January 1, 2011.”

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110-355, §7(b), Oct. 8, 2008, 122 Stat. 3995, provided that: “The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 8, 2008].”

Amendment by section 101(a)(1), (b)(1) of Pub. L. 110-275 applicable to services furnished on or after Jan. 1, 2009, see section 101(c) of Pub. L. 110-275, set out as a note under section 1395l of this title.

Amendment by section 125(b)(2) of Pub. L. 110-275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(d) of Pub. L. 110-275, set out as an Effective Date of 2008 Amendment; Transition Rule note under section 1395bb of this title.

Amendment by section 143(a), (b)(5), (6) of Pub. L. 110-275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110-275, set out as a note under section 1395k of this title.

Amendment by section 144(a)(1) of Pub. L. 110-275 applicable to items and services furnished on or after Jan. 1, 2010, see section 144(a)(3) of Pub. L. 110-275, set out as a note under section 1395w-4 of this title.

Amendment by section 152(b)(1)(A), (B) of Pub. L. 110-275 applicable to services furnished on or after Jan. 1, 2010, see section 152(b)(2) of Pub. L. 110-275, set out as a note under section 1395w-4 of this title.

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by section 5112(a), (b) of Pub. L. 109-171 applicable to services furnished on or after Jan. 1, 2007, see section 5112(f) of Pub. L. 109-171, set out as a note under section 1395l of this title.

Amendment by section 5114(a)(1), (b) of Pub. L. 109-171 applicable to services furnished on or after Jan.

1, 2006, see section 5114(c) of Pub. L. 109-171, set out as a note under section 1395u of this title.

Amendment by section 6001(f)(1) of Pub. L. 109-171 effective Feb. 8, 2006, see section 6001(f)(3) of Pub. L. 109-171, set out as a note under section 1396r-8 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 415(b) of Pub. L. 108-173 applicable to services furnished on or after Jan. 1, 2005, see section 415(c) of Pub. L. 108-173, set out as a note under section 1395m of this title.

Amendment by section 512(c) of Pub. L. 108-173 applicable to services provided by a hospice program on or after Jan. 1, 2005, see section 512(d) of Pub. L. 108-173, set out as a note under section 1395d of this title.

Amendment by section 611(a), (b), (d)(2) of Pub. L. 108-173 applicable to services furnished on or after Jan. 1, 2005, but only for individuals whose coverage period under this part begins on or after such date, see section 611(e) of Pub. L. 108-173, set out as a note under section 1395w-4 of this title.

Pub. L. 108-173, title VI, § 612(d), Dec. 8, 2003, 117 Stat. 2305, provided that: "The amendments made by this section [amending this section and section 1395y of this title] shall apply to tests furnished on or after January 1, 2005."

Pub. L. 108-173, title VI, § 613(d), Dec. 8, 2003, 117 Stat. 2306, provided that: "The amendments made by this section [amending this section and section 1395y of this title] shall apply to tests furnished on or after January 1, 2005."

Amendment by section 642(a) of Pub. L. 108-173 applicable to items furnished on or after Jan. 1, 2004, see section 642(c) of Pub. L. 108-173, set out as a note under section 1395l of this title.

Pub. L. 108-173, title IX, § 926(b)(2), Dec. 8, 2003, 117 Stat. 2396, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to discharge plans made on or after such date as the Secretary [of Health and Human Services] shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a) [enacting provisions set out as a note under this section]."

Amendment by section 946(a) of Pub. L. 108-173 applicable to hospice care provided on or after Dec. 8, 2003, see section 946(c) of Pub. L. 108-173, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106-554, § 1(a)(6) [title I, § 101(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-468, provided that: "The amendments made by subsection (a) [amending this section] shall apply to items and services furnished on or after July 1, 2001."

Pub. L. 106-554, § 1(a)(6) [title I, § 102(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A-468, provided that: "The amendments made by this section [amending this section and section 1395y of this title] shall apply to services furnished on or after January 1, 2002."

Amendment by section 1(a)(6) [title I, § 103(a)] of Pub. L. 106-554 applicable to colorectal cancer screening services provided on or after July 1, 2001, see section 1(a)(6) [title I, § 103(c)] of Pub. L. 106-554, set out as a note under section 1395m of this title.

Amendment by section 1(a)(6) [title I, § 105(a), (b)] of Pub. L. 106-554 applicable to services furnished on or after Jan. 1, 2002, see section 1(a)(6) [title I, § 105(e)] of Pub. L. 106-554, set out as a note under section 1395l of this title.

Pub. L. 106-554, § 1(a)(6) [title I, § 112(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-473, provided that: "The amendment made by subsection (a) [amending this section] shall apply to drugs and biologicals administered on or after the date of the enactment of this Act [Dec. 21, 2000]."

Pub. L. 106-554, § 1(a)(6) [title I, § 113(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A-473, provided that: "The amend-

ment made by subsection (a) [amending this section] shall apply to drugs furnished on or after the date of the enactment of this Act [Dec. 21, 2000]."

Amendment by section 1(a)(6) [title IV, § 430(b)] of Pub. L. 106-554 applicable to items and services furnished on or after July 1, 2001, see section 1(a)(6) [title IV, § 430(c)] of Pub. L. 106-554, set out as a note under section 1395l of this title.

Pub. L. 106-554, § 1(a)(6) [title IV, § 431(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-525, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to community mental health centers with respect to services furnished on or after the first day of the third month beginning after the date of the enactment of this Act [Dec. 21, 2000]."

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(6) [title II, § 201(k)] of Pub. L. 106-113 effective as if included in enactment of the Balanced Budget Act of 1997, Pub. L. 105-33, except as otherwise provided, see § 1000(a)(6) [title II, § 201(m)] of Pub. L. 106-113, set out as a note under section 1395l of this title.

Pub. L. 106-113, div. B, § 1000(a)(6) [title II, § 221(b)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A-351, provided that: "The amendments made by paragraph (1) [amending this section] apply to services furnished on or after January 1, 2000."

Pub. L. 106-113, div. B, § 1000(a)(6) [title III, § 303(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A-361, provided that: "The amendments made by this section [amending this section and section 1395fff of this title] shall apply to services furnished by home health agencies for cost reporting periods beginning on or after October 1, 1999."

Pub. L. 106-113, div. B, § 1000(a)(6) [title III, § 304(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A-361, provided that: "The amendments made by this section [enacting section 1320a-7f of this title and amending this section] take effect on the date of the enactment of this Act [Nov. 29, 1999], and in applying section 1861(o)(7) of the Social Security Act (42 U.S.C. 1395x(o)(7)), as amended by subsection (a), the Secretary of Health and Human Services may take into account the previous period for which a home health agency had a surety bond in effect under such section before such date."

Amendment by section 1000(a)(6) [title III, § 321(k)(7)-(9)] of Pub. L. 106-113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105-33, except as otherwise provided, see section 1000(a)(6) [title III, § 321(m)] of Pub. L. 106-113, set out as a note under section 1395d of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4102(a), (c) of Pub. L. 105-33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4102(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

Amendment by section 4103(a) of Pub. L. 105-33 applicable to items and services furnished on or after Jan. 1, 2000, see section 4103(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

Amendment by section 4104(a)(1) of Pub. L. 105-33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105-33, set out as a note under section 1395l of this title.

Amendment by section 4105(a)(1), (b)(1) of Pub. L. 105-33 applicable to items and services furnished on or after July 1, 1998, see section 4105(d)(1) of Pub. L. 105-33, set out as a note under section 1395m of this title.

Pub. L. 105-33, title IV, § 4106(d), Aug. 5, 1997, 111 Stat. 368, provided that: "The amendments made by this section [amending this section and sections 1395w-4, 1395aa, 1396a, and 1396n of this title] shall apply to bone mass measurements performed on or after July 1, 1998."

Amendment by section 4201(c)(1), (2) of Pub. L. 105-33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 105-33, set out as a note under section 1395f of this title.

Pub. L. 105-33, title IV, § 4205(b)(2), Aug. 5, 1997, 111 Stat. 376, provided that: "The amendment made by

paragraph (1) [amending this section] shall take effect on January 1, 1998.”

Pub. L. 105-33, title IV, § 4205(c)(2), Aug. 5, 1997, 111 Stat. 376, provided that: “The amendment made by paragraph (1) [amending this section] applies to waiver requests made on or after January 1, 1998.”

Pub. L. 105-33, title IV, § 4205(d)(4), Aug. 5, 1997, 111 Stat. 377, provided that:

“(A) IN GENERAL.—Except as otherwise provided, the amendments made by the preceding paragraphs [amending this section and section 1395u of this title] take effect on the date of the enactment of this Act [Aug. 5, 1997].

“(B) CURRENT RURAL HEALTH CLINICS.—The amendments made by the preceding paragraphs take effect, with respect to entities that are rural health clinics under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) on the date of enactment of this Act, on the date of the enactment of this Act [sic].

“(C) GRANDFATHERED CLINICS.—

“(i) IN GENERAL.—The amendment made by paragraph (3)(A) [amending this section] shall take effect on the effective date of regulations issued by the Secretary under clause (ii).

“(ii) REGULATIONS.—The Secretary shall issue final regulations implementing paragraph (3)(A) that shall take effect no later than January 1, 1999.”

Amendment by section 4312(d), (e) of Pub. L. 105-33 effective Aug. 5, 1997, and may be applied with respect to items and services furnished on or after Jan. 1, 1998, see section 4312(f)(3) of Pub. L. 105-33, set out as a note under section 1395m of this title.

Pub. L. 105-33, title IV, § 4312(f)(2), Aug. 5, 1997, 111 Stat. 388, provided that: “The amendments made by subsection (b) [amending this section] shall apply to home health agencies with respect to services furnished on or after January 1, 1998. The Secretary of Health and Human Services shall modify participation agreements under section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)) with respect to home health agencies to provide for implementation of such amendments on a timely basis.”

Pub. L. 105-33, title IV, § 4321(d)(1), Aug. 5, 1997, 111 Stat. 395, provided that: “The amendments made by subsection (a) [amending this section] shall apply to discharges occurring on or after the date which is 90 days after the date of the enactment of this Act [Aug. 5, 1997].”

Pub. L. 105-33, title IV, § 4404(b), Aug. 5, 1997, 111 Stat. 400, provided that: “The amendments made by subsection (a) [amending this section] apply to changes of ownership that occur after the third month beginning after the date of enactment of this section [Aug. 5, 1997].”

Amendment by section 4432(b)(5)(D), (E) of Pub. L. 105-33 applicable to items and services furnished on or after July 1, 1998, see section 4432(d) of Pub. L. 105-33, set out as a note under section 1395i-3 of this title.

Pub. L. 105-33, title IV, § 4444(b), Aug. 5, 1997, 111 Stat. 423, provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to items or services furnished on or after April 1, 1998.”

Amendment by sections 4445 and 4446 of Pub. L. 105-33 applicable to benefits provided on or after Aug. 5, 1997, except as otherwise provided, see section 4449 of Pub. L. 105-33, set out as a note under section 1395d of this title.

Amendment by section 4454(a)(1) of Pub. L. 105-33 effective Aug. 5, 1997, and applicable to items and services furnished on or after such date, with provision that Secretary of Health and Human Services issue regulations to carry out such amendment by not later than July 1, 1998, see section 4454(d) of Pub. L. 105-33, set out as an Effective Date note under section 1395i-5 of this title.

Amendment by section 4511(a)(1)-(2)(B), (d) of Pub. L. 105-33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4511(e) of Pub. L. 105-33, set out as a note under section 1395k of this title.

Amendment by section 4512(a) of Pub. L. 105-33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4512(d) of Pub. L. 105-33, set out as a note under section 1395l of this title.

Pub. L. 105-33, title IV, § 4513(b), Aug. 5, 1997, 111 Stat. 444, provided that: “The amendment made by subsection (a) [amending this section] applies to services furnished on or after January 1, 2000.”

Pub. L. 105-33, title IV, § 4557(b), Aug. 5, 1997, 111 Stat. 463, provided that: “The amendments made by subsection (a) [amending this section] shall apply to items and services furnished on or after January 1, 1998.”

Pub. L. 105-33, title IV, § 4604(c), Aug. 5, 1997, 111 Stat. 472, provided that: “The amendments made by this section [amending this section and section 1395bbb of this title] apply to cost reporting periods beginning on or after October 1, 1997.”

Amendment by section 4611(b) of Pub. L. 105-33 applicable to services furnished on or after Jan. 1, 1998, and for purposes of applying such amendment, any home health spell of illness that began, but did not end, before such date, to be considered to have begun as of such date, see section 4611(f) of Pub. L. 105-33, set out as a note under section 1395d of this title.

Pub. L. 105-33, title IV, § 4612(b), Aug. 5, 1997, 111 Stat. 474, provided that: “The amendment made by subsection (a) [amending this section] applies to services furnished on or after October 1, 1997.”

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-299 effective Oct. 1, 1996, see section 5 of Pub. L. 104-299, as amended, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Pub. L. 103-432, title I, § 107(b), Oct. 31, 1994, 108 Stat. 4407, provided that: “The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after the first day of the first month beginning more than one year after the date of the enactment of this Act [Oct. 31, 1994].”

Amendment by section 145(b) of Pub. L. 103-432 applicable to mammography furnished by the facility on and after the first date that the certificate requirements of section 263b(b) of this title apply to such mammography conducted by such facility, see section 145(d) of Pub. L. 103-432, set out as a note under section 1395m of this title.

Pub. L. 103-432, title I, § 146(c), Oct. 31, 1994, 108 Stat. 4429, provided that: “The amendments made by this section [amending this section] shall take effect on January 1, 1995.”

Amendment by section 147(e)(1), (4), (5), (f)(3), (4)(A), (6)(A), (B), (E) of Pub. L. 103-432 effective as if included in the enactment of Pub. L. 101-508, see section 147(g) of Pub. L. 103-432, set out as a note under section 1320a-3a of this title.

Pub. L. 103-432, title I, § 158(a)(2), Oct. 31, 1994, 108 Stat. 4442, provided that: “The amendment made by paragraph (1) [amending this section] shall apply with respect to cost reporting periods beginning on or after July 1, 1996.”

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103-66, title XIII, § 13503(c)(2), Aug. 10, 1993, 107 Stat. 579, provided that: “The amendments made by paragraph (1) [amending this section and section 1395oo of this title] shall take effect October 1, 1993.”

Pub. L. 103-66, title XIII, § 13553(c), Aug. 10, 1993, 107 Stat. 592, provided that: “The amendments made by subsections (a) and (b) [amending this section] shall apply to items furnished on or after January 1, 1994.”

Pub. L. 103-66, title XIII, § 13554(b), Aug. 10, 1993, 107 Stat. 592, provided that: “The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1994.”

Pub. L. 103-66, title XIII, § 13556(b), Aug. 10, 1993, 107 Stat. 592, provided that: “The amendments made by subsection (a) [amending this section] shall take effect

as if included in the enactment of section 4161(a)(2)(C) of OBRA-1990 [Pub. L. 101-508].”

Pub. L. 103-66, title XIII, §13564(b)(2), Aug. 10, 1993, 107 Stat. 607, provided that: “The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1993.”

Pub. L. 103-66, title XIII, §13566(c), Aug. 10, 1993, 107 Stat. 607, provided that: “The amendments made by this section [amending this section and section 1395rr of this title] shall apply to erythropoietin furnished on or after January 1, 1994.”

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 4008(h)(2)(A)(i) of Pub. L. 101-508 effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, see section 4008(h)(2)(P) of Pub. L. 101-508, set out as a note under section 1395i-3 of this title.

Amendment by section 4152(a)(2) of Pub. L. 101-508 applicable to items furnished on or after Jan. 1, 1991, see section 4152(a)(3) of Pub. L. 101-508, set out as a note under section 1395m of this title.

Pub. L. 101-508, title IV, §4153(b)(2)(C), Nov. 5, 1990, 104 Stat. 1388-84, provided that: “The amendments made by subparagraphs (A) and (B) [amending this section and section 1395y of this title] shall apply to items furnished on or after January 1, 1991.”

Amendment by section 4155(a), (d) of Pub. L. 101-508 applicable to services furnished on or after Jan. 1, 1991, see section 4155(e) of Pub. L. 101-508, set out as a note under section 1395k of this title.

Amendment by section 4157(a) of Pub. L. 101-508 applicable to services furnished on or after Jan. 1, 1991, see section 4157(d) of Pub. L. 101-508, set out as a note under section 1395k of this title.

Amendment by section 4161(a)(1), (2), (5) of Pub. L. 101-508 applicable to services furnished on or after Oct. 1, 1991, see section 4161(a)(8) of Pub. L. 101-508, set out as a note under section 1395k of this title.

Pub. L. 101-508, title IV, §4161(b)(5), Nov. 5, 1990, 104 Stat. 1388-95, provided that: “This subsection [amending this section and section 1395oo of this title and enacting provisions set out as a note below] shall take effect on October 1, 1991, except that the amendment made by paragraph (4) [amending section 1395oo of this title] shall apply to cost reports for periods beginning on or after October 1, 1991.”

Amendment by section 4162(a) of Pub. L. 101-508 applicable with respect to partial hospitalization services provided on or after Oct. 1, 1991, see section 4162(c) of Pub. L. 101-508, set out as a note under section 1395k of this title.

Amendment by section 4163(a) of Pub. L. 101-508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e) of Pub. L. 101-508, set out as a note under section 1395l of this title.

Pub. L. 101-508, title IV, §4201(d)(3)[(4)], Nov. 5, 1990, 104 Stat. 1388-104, provided that: “The amendments made by paragraphs (1) and (2) [amending this section and section 1395rr of this title] shall apply to items and services furnished on or after July 1, 1991.”

Pub. L. 101-508, title IV, §4207(d)(4), formerly §4027(d)(3), Nov. 5, 1990, 104 Stat. 1388-121, as renumbered and amended by Pub. L. 103-432, title I, §160(d)(4), (10), Oct. 31, 1994, 108 Stat. 4444, provided that: “The amendment made by paragraph (1) [amending this section] shall apply with respect to home health agency cost reporting periods beginning on or after July 1, 1991.”

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by section 6112(e)(1) of Pub. L. 101-239 applicable with respect to items furnished on or after Jan. 1, 1990, see section 6112(e)(4) of Pub. L. 101-239, set out as a note under section 1395m of this title.

Amendment by section 6113(a)-(b)(2) of Pub. L. 101-239 applicable to services furnished on or after July 1, 1990, see section 6113(e) of Pub. L. 101-239, set out as a note under section 1395l of this title.

Amendment by section 6114(a), (d) of Pub. L. 101-239 applicable to services furnished on or after Apr. 1, 1990, see section 6114(f) of Pub. L. 101-239, set out as a note under section 1395u of this title.

Pub. L. 101-239, title VI, §6115(d), Dec. 19, 1989, 103 Stat. 2219, provided that: “The amendments made by this section [amending this section and sections 1395y, 1395aa, 1395bb, 1396a, and 1396n of this title] shall apply to screening pap smears performed on or after July 1, 1990.”

Amendment by section 6131(a)(2) of Pub. L. 101-239 applicable with respect to therapeutic shoes and inserts furnished on or after July 1, 1989, with additional provisions regarding applicability of the increase under section 1395(o)(2)(C) of this title, see section 6131(c) of Pub. L. 101-239, set out as a note under section 1395l of this title.

Pub. L. 101-239, title VI, §6141(b), Dec. 19, 1989, 103 Stat. 2225, provided that: “The amendments made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].”

Pub. L. 101-239, title VI, §6213(d), Dec. 19, 1989, 103 Stat. 2251, as amended by Pub. L. 101-508, title IV, §4207(k)(4), formerly §4027(k)(4), Nov. 5, 1990, 104 Stat. 1388-125, renumbered Pub. L. 103-432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that: “The amendments made by subsections (a) through (c) of this section [amending this section] shall apply to services furnished on or after October 1, 1989.”

Amendment by section 101(a) of Pub. L. 101-234 effective Jan. 1, 1990, see section 101(d) of Pub. L. 101-234, set out as a note under section 1395c of this title.

Amendment by section 201(a) of Pub. L. 101-234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101-234, set out as a note under section 1320a-7a of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100-647, title VIII, §8423(b), Nov. 10, 1988, 102 Stat. 3803, provided that: “The amendments made by subsection (a) [amending this section] shall be effective with respect to services furnished on or after January 1, 1989.”

Pub. L. 100-647, title VIII, §8424(b), Nov. 10, 1988, 102 Stat. 3803, provided that: “The amendment made by subsection (a) [amending this section] shall become effective with respect to services provided after December 31, 1988.”

Amendment by Pub. L. 100-485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100-360, see section 608(g)(1) of Pub. L. 100-485, set out as a note under section 704 of this title.

Amendment by section 104(d)(4) of Pub. L. 100-360 effective Jan. 1, 1989, except as otherwise provided, and applicable to inpatient hospital deductible for 1989 and succeeding years, to care and services furnished on or after Jan. 1, 1989, to premiums for January 1989 and succeeding months, and to blood or blood cells furnished on or after Jan. 1, 1989, see section 104(a) of Pub. L. 100-360, set out as a note under section 1395d of this title.

Amendment by section 202(a) of Pub. L. 100-360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(m)(1) of Pub. L. 100-360, set out as a note under section 1395u of this title.

Amendment by section 203(b), (e)(1) of Pub. L. 100-360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100-360, set out as a note under section 1320c-3 of this title.

Amendment by section 204(a) of Pub. L. 100-360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100-360, set out as a note under section 1395m of this title.

Amendment by section 205(b) of Pub. L. 100-360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(f) of Pub. L. 100-360, set out as a note under section 1395k of this title.

Pub. L. 100-360, title II, §206(b), July 1, 1988, 102 Stat. 732, which provided that the amendment of this section

by section 206(a) of Pub. L. 100-360 applied to services furnished in cases of initial periods of home health services beginning on or after January 1, 1990, was repealed by Pub. L. 101-234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

Except as specifically provided in section 411 of Pub. L. 100-360, amendment by section 411(d)(5)(A), (g)(3)(H), (h)(1)(B)-(3)(A), (4)(D), (5)-(7)(A), (E), (F), (i)(3), (4)(C)(iii), (l)(1)(B), (C) of Pub. L. 100-360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203, effective as if included in the enactment of that provision in Pub. L. 100-203, see section 411(a) of Pub. L. 100-360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Pub. L. 100-360, title IV, §411(d)(1)(B)(ii), July 1, 1988, 102 Stat. 773, provided that: "The amendment made by clause (i) [amending this section] shall apply to equipment furnished on or after the effective date provided in section 4021(c) of OBRA [Pub. L. 100-203, set out below]."

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100-203, title IV, §4009(e)(2), Dec. 22, 1987, 101 Stat. 1330-58, provided that: "The amendment made by paragraph (1) [amending this section] shall apply with respect to services furnished on or after April 1, 1988."

Pub. L. 100-203, title IV, §4021(c), Dec. 22, 1987, 101 Stat. 1330-69, provided that: "Except as otherwise provided, the amendments made by subsections (a) and (b) [enacting section 1395bbb of this title and amending this section] shall apply to home health agencies as of the first day of the 18th calendar month that begins after the date of the enactment of this Act [Dec. 22, 1987]."

Pub. L. 100-203, title IV, §4026(a)(2), Dec. 22, 1987, 101 Stat. 1330-75, as amended by Pub. L. 100-360, title IV, §411(d)(5)(B), July 1, 1988, 102 Stat. 775, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after July 1, 1989."

Pub. L. 100-203, title IV, §4064(e)(2), Dec. 22, 1987, 101 Stat. 1330-112, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to diagnostic tests performed on or after January 1, 1990."

Pub. L. 100-203, title IV, §4065(c), Dec. 22, 1987, 101 Stat. 1330-112, provided that: "The amendments made by this section [amending this section and section 1395rr of this title] shall become effective on January 1, 1988."

Pub. L. 100-203, title IV, §4070(c)(2), Dec. 22, 1987, 101 Stat. 1330-115, provided that:

"(A) The amendments made by subsection (b) [amending this section and sections 1395l and 1395n of this title] shall become effective on the date of enactment of this Act [Dec. 22, 1987].

"(B) The Secretary of Health and Human Services shall implement the amendments made by subsection (b) so as to ensure that there is no additional cost to the medicare program by reason of such amendments."

Pub. L. 100-203, title IV, §4071(b), Dec. 22, 1987, 101 Stat. 1330-116, provided that:

"(1) The provisions of subsection (e) of section 4072 of this subpart [section 4072(e) of Pub. L. 100-203, set out below] shall apply to this section [amending this section] in the same manner as it applies to section 4072. [Amendments became effective pursuant to final report dated Apr. 26, 1993. See Cong. Rec., vol. 139, pt. 7, p. 10460, Ex. Comm. 1254.]

"(2) In conducting the demonstration project pursuant to paragraph (1), in order to determine the cost effectiveness of including influenza vaccine in the medicare program, the Secretary of Health and Human Services is required to conduct a demonstration of the provision of influenza vaccine as a service for medicare beneficiaries and to expend \$25,000,000 each year of the demonstration project for this purpose. In conducting this demonstration, the Secretary is authorized to purchase in bulk influenza vaccine and to distribute it in a manner to make it widely available to medicare bene-

ficiaries, to develop projects to provide vaccine in the same manner as other covered medicare services in large scale demonstration projects, including statewide projects, and to engage in other appropriate use of moneys to provide influenza vaccine to medicare beneficiaries and evaluate the cost effectiveness of its use. In determining cost effectiveness, the Secretary shall consider the direct cost of the vaccine, the utilization of vaccine which might otherwise not have occurred, the costs of illnesses and nursing home days avoided, and other relevant factors, except that extended life for beneficiaries shall not be considered to reduce the cost effectiveness of the vaccine."

Pub. L. 100-203, title IV, §4072(e), Dec. 22, 1987, 101 Stat. 1330-117, provided that:

"(1) The amendments made by this section [amending this section and sections 1395f, 1395y, 1395aa, 1395bb, 1396a, and 1396n of this title] shall become effective (if at all) in accordance with paragraph (2).

"(2)(A) The Secretary of Health and Human Services (in this paragraph referred to as the 'Secretary'), shall establish a demonstration project to begin on October 1, 1988, to test the cost-effectiveness of furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section to a sample group of medicare beneficiaries.

"(B)(i) The demonstration project under subparagraph (A) shall be conducted for an initial period of 24 months. Not later than October 1, 1990, the Secretary shall report to the Congress on the results of such project. If the Secretary finds, on the basis of existing data, that furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section is cost-effective, the Secretary shall include such finding in such report, such project shall be discontinued, and the amendments made by this section shall become effective on November 1, 1990.

"(ii) If the Secretary determines that such finding cannot be made on the basis of existing data, such project shall continue for an additional 24 months. Not later than April 1, 1993, the Secretary shall submit a final report to the Congress on the results of such project. The amendments made by this section shall become effective on the first day of the first month to begin after such report is submitted to the Congress unless the report contains a finding by the Secretary that furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section is not cost-effective (in which case the amendments made by this section shall not become effective)."

[Amendments by section 4072 of Pub. L. 100-203 became effective pursuant to final report dated Apr. 26, 1993. See Cong. Rec., vol. 139, pt. 7, p. 10460, Ex. Comm. 1252.]

Amendment by section 4073(a), (c) of Pub. L. 100-203 effective with respect to services performed on or after July 1, 1988, see section 4073(e) of Pub. L. 100-203, set out as a note under section 1395k of this title.

Pub. L. 100-203, title IV, §4074(c), Dec. 22, 1987, 101 Stat. 1330-120, provided that: "The amendments made by this section [amending this section] shall be effective with respect to services performed on or after January 1, 1988."

Pub. L. 100-203, title IV, §4075(b), Dec. 22, 1987, 101 Stat. 1330-120, provided that: "The amendment made by subsection (a) [amending this section] shall apply to drugs dispensed on or after the date of the enactment of this Act [Dec. 22, 1987]."

Pub. L. 100-203, title IV, §4076(b), Dec. 22, 1987, 101 Stat. 1330-120, provided that: "The amendments made by this section [amending this section] shall apply with respect to services furnished on or after January 1, 1989."

Pub. L. 100-203, title IV, §4077(a)(2), Dec. 22, 1987, 101 Stat. 1330-120, provided that: "The amendment made by paragraph (1) [amending this section] shall be effective with respect to services furnished on or after the date of enactment of this Act [Dec. 22, 1987]."

Amendment by section 4077(b)(1), (4) of Pub. L. 100-203 effective with respect to services performed on or after July 1, 1988, see section 4077(b)(5) of Pub. L. 100-203, as amended, set out as a note under section 1395k of this title.

Amendment by section 4084(c)(1) of Pub. L. 100-203 applicable to services furnished after Dec. 31, 1988, see section 4084(c)(3) of Pub. L. 100-203, as added, set out as a note under section 1395f of this title.

Amendments by section 4201(a)(1), (b)(1), (d)(1), (2), (5) of Pub. L. 100-203 applicable to services furnished on or after Oct. 1, 1990, without regard to whether regulations to implement such amendments are promulgated by such date, except as otherwise specifically provided in section 1395i-3 of this title, see section 4204(a) of Pub. L. 100-203, as amended, set out as an Effective Date note under section 1395i-3 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99-509, title IX, §9305(c)(4), Oct. 21, 1986, 100 Stat. 1990, provided that: "The amendments made by this subsection [amending this section and section 1395bb of this title] shall apply to hospitals as of one year after the date of the enactment of this Act [Oct. 21, 1986]."

Pub. L. 99-509, title IX, §9313(a)(3), Oct. 21, 1986, 100 Stat. 2002, provided that: "The amendments made by this paragraph [probably means "this subsection" which amended this section and section 1395ff of this title] take effect on the date of the enactment of this Act [Oct. 21, 1986]."

Amendment by section 9320(b), (c), (f) of Pub. L. 99-509 applicable to services furnished on or after Jan. 1, 1989, with exceptions for hospitals located in rural areas which meet certain requirements related to certified registered nurse anesthetists, see section 9320(i), (k) of Pub. L. 99-509, as amended, set out as notes under section 1395k of this title.

Pub. L. 99-509, title IX, §9335(c)(2), Oct. 21, 1986, 100 Stat. 2030, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to immunosuppressive drugs furnished on or after January 1, 1987."

Pub. L. 99-509, title IX, §9336(b), Oct. 21, 1986, 100 Stat. 2033, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1987."

Amendment by section 9337(d) of Pub. L. 99-509 applicable to expenses incurred for outpatient occupational therapy services furnished on or after July 1, 1987, see section 9337(e) of Pub. L. 99-509, set out as a note under section 1395k of this title.

Pub. L. 99-509, title IX, §9338(f), Oct. 21, 1986, 100 Stat. 2036, provided that: "The amendments made by this section [amending this section and section 1395u of this title] shall apply to services furnished on or after January 1, 1987."

Pub. L. 99-272, title IX, §9107(c)(2), Apr. 7, 1986, 100 Stat. 161, provided that: "The amendments made by subsection (b) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1985."

Pub. L. 99-272, title IX, §9110(b), Apr. 7, 1986, 100 Stat. 162, provided that: "The amendments made by subsection (a) [amending this section] shall be applied as though they were originally included in the Deficit Reduction Act of 1984 [Pub. L. 98-369]."

Pub. L. 99-272, title IX, §9202(i)(2), Apr. 7, 1986, 100 Stat. 177, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after July 1, 1985."

Amendment by section 9219(b)(1)(B) of Pub. L. 99-272 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L. 98-369, see section 9219(b)(1)(D) of Pub. L. 99-272, set out as a note under section 1395u of this title.

Pub. L. 99-272, title IX, §9219(b)(3)(B), Apr. 7, 1986, 100 Stat. 183, provided that: "The amendment made by subparagraph (A) [amending this section] shall be effective

as if it had been originally included in the Social Security Amendments of 1983 [Pub. L. 98-21]."

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-617 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L. 98-369, see section 3(c) of Pub. L. 98-617, set out as a note under section 1395f of this title.

Pub. L. 98-369, div. B, title III, §2314(c)(1), (2), July 18, 1984, 98 Stat. 1079, provided that:

"(1) Clause (i) of section 1861(v)(1)(O) of the Social Security Act [42 U.S.C. 1395x(v)(1)(O)(i)] shall not apply to changes of ownership of assets pursuant to an enforceable agreement entered into before the date of the enactment of this Act [July 18, 1984].

"(2) Clause (iii) of section 1861(v)(1)(O) of such Act [42 U.S.C. 1395x(v)(1)(O)(iii)] shall apply to costs incurred on or after the date of the enactment of this Act."

Pub. L. 98-369, div. B, title III, §2318(c), July 18, 1984, 98 Stat. 1082, provided that: "The amendments made by this section [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2319(a) of Pub. L. 98-369 applicable to cost reporting periods beginning on or after July 1, 1984, see section 2319(c) of Pub. L. 98-369, set out as an Effective Date note under section 1395yy of this title.

Amendment by section 2321(e) of Pub. L. 98-369 applicable to items and services furnished on or after July 18, 1984, see section 2321(g) of Pub. L. 98-369, set out as a note under section 1395f of this title.

Pub. L. 98-369, div. B, title III, §2322(b), July 18, 1984, 98 Stat. 1086, provided that: "The amendments made by subsection (a) [amending this section] shall be effective with respect to services furnished on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2323(a) of Pub. L. 98-369 applicable to services furnished on or after Sept. 1, 1984, see section 2323(d) of Pub. L. 98-369, set out as a note under section 1395f of this title.

Pub. L. 98-369, div. B, title III, §2324(b), July 18, 1984, 98 Stat. 1087, provided that: "The amendments made by subsection (a) [amending this section] shall be effective with respect to items and services purchased on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2335(b) of Pub. L. 98-369 effective July 18, 1984, see section 2335(g) of Pub. L. 98-369, set out as a note under section 1395f of this title.

Pub. L. 98-369, div. B, title III, §2340(c), July 18, 1984, 98 Stat. 1093, provided that: "The amendments made by this section [amending this section and section 1396d of this title] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2341(a), (c) of Pub. L. 98-369 applicable to services furnished on or after July 18, 1984, see section 2341(d) of Pub. L. 98-369, set out as a note under section 1395k of this title.

Amendment by section 2342(a) of Pub. L. 98-369 applicable to plans of care established on or after July 18, 1984, see section 2342(c) of Pub. L. 98-369, set out as a note under section 1395n of this title.

Pub. L. 98-369, div. B, title III, §2343(c), July 18, 1984, 98 Stat. 1095, provided that: "The amendments made by subsections (a) and (b) [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2354(b)(18)-(29) of Pub. L. 98-369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98-369, set out as a note under section 1320a-1 of this title.

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by section 602(d) of Pub. L. 98-21 applicable to items and services furnished by or under arrange-

ment with a hospital beginning with its first cost reporting period that begins on or after Oct. 1, 1983, any change in a hospital's cost reporting period made after November 1982 to be recognized for such purposes only if the Secretary finds good cause therefor, see section 604(a)(1) of Pub. L. 98-21, set out as a note under section 1395ww of this title.

Amendment by Pub. L. 97-448 effective as if originally included in the provision of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248, to which such amendment relates, see section 309(c)(1) of Pub. L. 97-448, set out as a note under section 426 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by section 101(a)(2) of Pub. L. 97-248 applicable to cost reporting periods beginning on or after Oct. 1, 1982, see section 101(b)(1) of Pub. L. 97-248, set out as an Effective Date note under section 1395ww of this title.

Pub. L. 97-248, title I, §102(b), Sept. 3, 1982, 96 Stat. 336, as amended by Pub. L. 98-21, title VI, §605(a), Apr. 20, 1983, 97 Stat. 169, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to cost reporting periods beginning on or after October 1, 1983."

Pub. L. 97-248, title I, §103(b), Sept. 3, 1982, 96 Stat. 336, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to cost reporting periods ending after September 30, 1982, but in the case of any cost reporting period beginning before October 1, 1982, any reduction in payments under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] to a hospital or skilled nursing facility resulting from such amendment shall be imposed only in proportion to the part of the period which occurs after September 30, 1982."

Pub. L. 97-248, title I, §105(b), Sept. 3, 1982, 96 Stat. 337, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to cost reporting periods beginning on or after the date of the enactment of this Act [Sept. 3, 1982]."

Pub. L. 97-248, title I, §106(b), Sept. 3, 1982, 96 Stat. 337, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to any costs incurred under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], except that it shall not apply to costs which have been allowed prior to the date of the enactment of this Act [Sept. 3, 1982] pursuant to the final court order affirmed by a United States Court of Appeals."

Pub. L. 97-248, title I, §107(b), Sept. 3, 1982, 96 Stat. 337, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to costs incurred after the date of the enactment of this Act [Sept. 3, 1982]."

Amendment by section 109(b)(2) of Pub. L. 97-248 effective Sept. 3, 1982, see section 109(c)(1) of Pub. L. 97-248, set out as a note under section 1395xx of this title.

Pub. L. 97-248, title I, §109(c)(3), Sept. 3, 1982, 96 Stat. 339, provided that: "The amendment made by subsection (b)(1) [amending this section] shall not apply to contracts entered into before the date of the enactment of this Act [Sept. 3, 1982]."

Amendment by section 122(d) of Pub. L. 97-248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97-248, as amended, set out as a note under section 1395c of this title.

Pub. L. 97-248, title I, §128(e), Sept. 3, 1982, 96 Stat. 367, as amended by Pub. L. 99-514, §2, Oct. 22, 1986, 100 Stat. 2095, provided that:

"(1) Any amendment to the Omnibus Budget Reconciliation [Reconciliation] Act of 1981 [Pub. L. 97-35] made by this section [amending provisions set out as notes under sections 426 and 1395x of this title] shall be effective as if it had been originally included in the provision of the Omnibus Budget Reconciliation Act of 1981 to which such amendment relates.

"(2) Except as otherwise provided in this section, any amendment to the Social Security Act [42 U.S.C. 301 et

seq.] or the Internal Revenue Code of 1986 [formerly I.R.C. 1954] [Title 26, Internal Revenue Code] made by this section (other than subsection (d)) [amending this section and sections 1395y, 1395cc, and 1395uu of this title and section 162 of Title 26] shall be effective as if it had been originally included as a part of that provision of the Social Security Act or Internal Revenue Code of 1986 to which it relates, as such provision of such Act or Code was amended by the Omnibus Budget Reconciliation [Reconciliation] Act of 1981 [Pub. L. 97-35].

"(3) The amendments made by subsection (d) [amending this section and sections 1395u, 1395bb, 1395cc, and 1395gg of this title] shall take effect upon enactment [Sept. 3, 1982]."

Amendment by section 148(b) of Pub. L. 97-248 effective with respect to contracts entered into or renewed on or after Sept. 3, 1982, see section 149 of Pub. L. 97-248, set out as an Effective Date note under section 1320c of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97-35, title XXI, §2102(b)(1), Aug. 13, 1981, 95 Stat. 787, provided that: "The amendments made by subsection (a) [amending this section], shall apply to services provided on or after the first day of the first month beginning after the date of the enactment of this Act [Aug. 13, 1981]."

Amendment by section 2121(c), (d) of Pub. L. 97-35 applicable to services furnished in detoxification facilities for inpatient stays beginning on or after the tenth day after Aug. 13, 1981, see section 2121(i) of Pub. L. 97-35, set out as a note under section 1395d of this title.

Pub. L. 97-35, title XXI, §2141(c), Aug. 13, 1981, 95 Stat. 798, provided that:

"(1) Subject to paragraph (2), the amendment made by subsection (a) [amending this section] shall apply to cost reporting periods ending after September 30, 1981.

"(2) In the case of a cost reporting period beginning before October 1, 1981, any reduction in payments resulting from the amendment made by subsection (a) shall be imposed only in proportion to the part of the period that occurs after September 30, 1981."

Pub. L. 97-35, title XXI, §2143(b), Aug. 13, 1981, 95 Stat. 799, as amended by Pub. L. 97-248, title I, §128(c)(1), Sept. 3, 1982, 96 Stat. 367, provided that:

"(1) Subject to paragraph (2), the amendment made by subsection (a) [amending this section] shall apply to cost reporting periods ending after September 30, 1981.

"(2) In the case of a cost reporting period beginning before October 1, 1981, any reduction in payments resulting from the amendment made by subsection (a) shall be imposed only in proportion to the part of the period that occurs after September 30, 1981."

Pub. L. 97-35, title XXI, §2144(b), Aug. 13, 1981, 95 Stat. 799, provided that:

"(1) Subject to paragraph (2), the amendment made by subsection (a) [amending this section] shall apply to cost reporting periods ending after September 30, 1981.

"(2) In the case of a cost reporting period beginning before October 1, 1981, any reduction in payments resulting from the amendment made by subsection (a) shall be imposed only in proportion to the part of the period that occurs after September 30, 1981."

For effective date, savings, and transitional provisions relating to amendment by section 2193(c)(9) of Pub. L. 97-35, see section 2194 of Pub. L. 97-35, set out as a note under section 701 of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96-611 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96-611, set out as a note under section 1395l of this title.

Pub. L. 96-499, title IX, §902(c), Dec. 5, 1980, 94 Stat. 2614, provided that: "The amendments made by this section [amending this section and sections 1320c-7 and 1396a of this title] shall become effective on the date of [probably should be "on"] which final regulations, pro-

mulgated by the Secretary to implement such amendments, are first issued; and those regulations shall be issued not later than the first day of the sixth month following the month in which this Act is enacted [December 1980].”

Pub. L. 96-499, title IX, §930(s), Dec. 5, 1980, 94 Stat. 2633, provided that:

“(1) the amendments made by this section [amending this section, sections 426, 1395c, 1395d, 1395f, 1395h, 1395k, 1395l, and 1395n of this title, and section 231f of Title 45, Railroads, and repealing section 1395m of this title] shall become effective with respect to services furnished on or after July 1, 1981, except that the amendments made by subsections (n)(1) and (o) [amending this section and section 1395h of this title] shall become effective on the date of the enactment of this Act [Dec. 5, 1980].

“(2) The Secretary of Health and Human Services shall take administrative action to assure that improvements, in accordance with the amendment made by subsection (n)(1) [amending this section], will be made not later than June 30, 1981.”

Amendment by section 931(c), (d) of Pub. L. 96-499 effective Apr. 1, 1981, see section 931(e) of Pub. L. 96-499, set out as a note under section 1395d of this title.

Amendment by section 933(c)-(e) of Pub. L. 96-499 effective with respect to a comprehensive outpatient rehabilitation facility's first accounting period beginning on or after July 1, 1981, see section 933(h) of Pub. L. 96-499, set out as a note under section 1395k of this title.

Amendment by section 936(a) of Pub. L. 96-499 applicable with respect to services provided on or after July 1, 1981, see section 936(d) of Pub. L. 96-499, set out as a note under section 1395f of this title.

Pub. L. 96-499, title IX, §937(c), Dec. 5, 1980, 94 Stat. 2640, as amended by Pub. L. 98-369, div. B, title III, §2354(c)(1)(B), July 18, 1984, 98 Stat. 1102, provided that: “The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 1981.”

Pub. L. 96-499, title IX, §938(b), Dec. 5, 1980, 94 Stat. 2640, provided that: “The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1981.”

Pub. L. 96-499, title IX, §948(c)(1), Dec. 5, 1980, 94 Stat. 2644, provided that: “The amendments made by subsection (a) [amending this section and section 1395k of this title] shall apply with respect to cost accounting periods beginning on or after October 1, 1978. A hospital's election under section 1861(b)(7)(A) of the Social Security Act [42 U.S.C. 1395x(b)(7)(A)] (as administered in accordance with section 15 of Public Law 93-233) as of September 30, 1978, shall constitute such hospital's election under such section (as amended by subsection (a)(1)) on and after October 1, 1978, until otherwise provided by the hospital.”

Pub. L. 96-499, title IX, §951(c), Dec. 5, 1980, 94 Stat. 2646, provided that: “The amendments made by this section [amending this section] shall take effect on January 1, 1981.”

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility's or provider's first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95-292, set out as a note under section 426 of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95-216, title V, §501(c), Dec. 20, 1977, 91 Stat. 1565, provided that: “The amendments made by this

section [amending this section and section 1395u of this title] shall be effective in the case of items and services furnished after the date of the enactment of this Act [Dec. 20, 1977].”

Amendment by Pub. L. 95-210 applicable to services rendered on or after the first day of the third calendar month which begins after Dec. 31, 1977, see section 1(j) of Pub. L. 95-210, set out as a note under section 1395k of this title.

Amendment by section 3(a)(2) of Pub. L. 95-142 effective Oct. 25, 1977, see section 3(e) of Pub. L. 95-142, set out as an Effective Date note under section 1320a-3 of this title.

Amendment by section 19(b)(1) of Pub. L. 95-142 effective with respect to operation of a hospital, skilled nursing facility, or intermediate care facility on and after the first day of its first fiscal year which begins after the end of the six-month period beginning on the date a uniform reporting system is established under section 1320a(a) of this title for that type of health services facility, except that for other types of facilities or organizations effective with respect to operations on and after the first day of its first fiscal year which begins after such date as the Secretary determines to be appropriate for the implementation of the reporting requirement for that type of facility or organization, see section 19(c)(2) of Pub. L. 95-142, set out as a note under section 1396a of this title.

Pub. L. 95-142, §21(c)(1), Oct. 25, 1977, 91 Stat. 1208, provided that: “The amendments made by subsection (a) [amending this section] shall be effective on the first day of the first calendar quarter which begins more than six months after the date of enactment of this Act [Oct. 25, 1977].”

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94-182, title I, §106(b), Dec. 31, 1975, 89 Stat. 1052, provided that: “Subject to subsection (c) [enacting provisions set out below], the amendment made by subsection (a) [amending this section] shall be effective on the first day of the sixth month which begins after the date of enactment of this Act [Dec. 31, 1975].”

Pub. L. 94-182, title I, §112(d), Dec. 31, 1975, 89 Stat. 1055, provided that: “The amendments made by this section [amending this section and sections 1320c-17 and 1395g of this title] shall be effective with respect to utilization review activities conducted on and after the first day of the first month which begins more than 30 days after the date of enactment of this Act [Dec. 31, 1975].”

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by section 211(b), (c)(2) of Pub. L. 92-603 applicable to services furnished with respect to admissions occurring after Dec. 31, 1972, see section 211(d) of Pub. L. 92-603, set out as a note under section 1395f of this title.

Pub. L. 92-603, title II, §223(h), Oct. 31, 1972, 86 Stat. 1394, provided that: “The amendments made by this section [amending this section and section 1395cc of this title] shall be effective with respect to accounting periods beginning after December 31, 1972.”

Pub. L. 92-603, title II, §227(g), Oct. 31, 1972, 86 Stat. 1407, provided that: “The amendments made by this section [amending this section and sections 1395f, 1395k, 1395n, 1395u, and 1395cc of this title] shall apply with respect to accounting periods beginning after June 30, 1973.”

Pub. L. 92-603, title II, §234(i), Oct. 31, 1972, 86 Stat. 1414, provided that: “The amendments made by this section [amending this section and sections 1395f, 1395z, and 1395bb of this title] shall apply with respect to any provider of services for fiscal years (of such provider) beginning after the fifth month following the month in which this Act is enacted [October 1972].”

Pub. L. 92-603, title II, §246(c), Oct. 31, 1972, 86 Stat. 1425, provided that: “The amendments made by this section [amending this section and section 1396 of this title] shall be effective July 1, 1973.”

Pub. L. 92-603, title II, §251(d), Oct. 31, 1972, 86 Stat. 1446, as amended by Pub. L. 93-233, §17(a), Dec. 31, 1973, 87 Stat. 967, provided that:

“(1) The amendments made by subsection (a) [amending this section and sections 1395l and 1395k of this title] shall apply with respect to services furnished on or after July 1, 1973.

“(2) The amendments made by subsection (b) [amending this section and section 1395n of this title] shall apply with respect to services furnished on or after the date of enactment of this Act [Oct. 30, 1972].

“(3) The amendments made by subsection (c) [amending this section] shall be effective with respect to accounting periods beginning after the month in which there are promulgated, by the Secretary of Health, Education, and Welfare, final regulations implementing the provisions of section 1861(v)(5) of the Social Security Act [42 U.S.C. 1395x(v)(5)].”

Pub. L. 92-603, title II, §252(b), Oct. 31, 1972, 86 Stat. 1446, provided that: “The amendment made by subsection (a) [amending this section] shall apply only with respect to items furnished on or after the date of the enactment of this Act [Oct. 30, 1972].”

Amendment by section 256(b) of Pub. L. 92-603 applicable with respect to admissions occurring after the second month following the month of enactment of Pub. L. 92-603 which was approved on Oct. 30, 1972, see section 256(d) of Pub. L. 92-603, set out as a note under section 1395f of this title.

Pub. L. 92-603, title II, §264(b), Oct. 31, 1972, 86 Stat. 1449, provided that: “The amendment made by subsection (a) [amending this section] shall apply only with respect to services performed on or after the date of the enactment of this Act [Oct. 30, 1972].”

Pub. L. 92-603, title II, §273(b), Oct. 31, 1972, 86 Stat. 1452, provided that: “The amendments made by this section [amending this section] shall be effective with respect to services furnished after June 30, 1973.”

Pub. L. 92-603, title II, §276(b), Oct. 31, 1972, 86 Stat. 1452, provided that: “The amendment made by this section [amending this section] shall apply with respect to accounting periods beginning after December 31, 1972.”

Amendment by section 283(a) of Pub. L. 92-603 to apply with respect to services rendered after Dec. 31, 1972, see section 283(c) of Pub. L. 92-603, set out as a note under section 1395n of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Pub. L. 90-248, title I, §127(c), Jan. 2, 1968, 81 Stat. 847, provided that: “The amendments made by subsections (a) and (b) [amending this section and section 1395y of this title] shall apply with respect to services furnished after December 31, 1967.”

Amendment by section 129(a), (b), (c)(9)(C), (10), (11) of Pub. L. 90-248 applicable with respect to services furnished after Mar. 31, 1968, see section 129(d) of Pub. L. 90-248, set out as a note under section 1395d of this title.

Amendment by section 132(a) of Pub. L. 90-248 applicable with respect to items purchased after Dec. 31, 1967, see section 132(c) of Pub. L. 90-248, set out as a note under section 1395l of this title.

Amendment by section 133(a), (b) of Pub. L. 90-248 applicable with respect to services furnished after June 30, 1968, see section 133(g) of Pub. L. 90-248, set out as a note under section 1395k of this title.

Pub. L. 90-248, title I, §134(b), Jan. 2, 1968, 81 Stat. 852, provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to services furnished after December 31, 1967.”

Amendment by section 143(a) of Pub. L. 90-248 effective July 1, 1966, see section 143(d) of Pub. L. 90-248, set out as a note under section 1395d of this title.

Pub. L. 90-248, title I, §144(e), Jan. 2, 1968, 81 Stat. 859, provided that: “The amendments made by this section [amending this section] shall apply with respect to services furnished after March 31, 1968.”

EFFECTIVE DATE OF 1966 AMENDMENT

Amendment by Pub. L. 89-713 effective Nov. 2, 1966, see section 6 of Pub. L. 89-713, set out as a note under section 6091 of Title 26, Internal Revenue Code.

CONSTRUCTION OF 2018 AMENDMENT

Pub. L. 115-271, title II, §2002(c), Oct. 24, 2018, 132 Stat. 3926, provided that: “Nothing in the amendments made by subsection (a) or (b) [amending this section] shall be construed to prohibit separate payment for structured assessment and intervention services for substance abuse furnished to an individual on the same day as an initial preventive physical examination or an annual wellness visit.”

CONSTRUCTION OF 2008 AMENDMENT

For construction of amendment by section 153(b)(3)(B) of Pub. L. 110-275, see section 153(b)(4) of Pub. L. 110-275, set out as a note under section 1395rr of this title.

CONFORMING REFERENCES TO PREVIOUS PART D

Pub. L. 108-173, title I, §101(e)(1), Dec. 8, 2003, 117 Stat. 2150, provided that: “Any reference in law (in effect before the date of the enactment of this Act [Dec. 8, 2003]) to part D of title XVIII of the Social Security Act [42 U.S.C. 1395w-101 et seq.] is deemed a reference to part E of such title [42 U.S.C. 1395x et seq.] (as in effect after such date).”

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 108-173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108-173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108-173 (see note above), amendment by section 303 of Pub. L. 108-173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108-173, set out as a note under section 1395u of this title.

FRONTIER EXTENDED STAY CLINIC DEMONSTRATION PROJECT

Pub. L. 108-173, title IV, §434, Dec. 8, 2003, 117 Stat. 2288, provided that:

“(a) AUTHORITY TO CONDUCT DEMONSTRATION PROJECT.—The Secretary [of Health and Human Services] shall waive such provisions of the medicare program established under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as are necessary to conduct a demonstration project under which frontier extended stay clinics described in subsection (b) in isolated rural areas are treated as providers of items and services under the medicare program.

“(b) CLINICS DESCRIBED.—A frontier extended stay clinic is described in this subsection if the clinic—

“(1) is located in a community where the closest short-term acute care hospital or critical access hospital is at least 75 miles away from the community or is inaccessible by public road; and

“(2) is designed to address the needs of—

“(A) seriously or critically ill or injured patients who, due to adverse weather conditions or other reasons, cannot be transferred quickly to acute care referral centers; or

“(B) patients who need monitoring and observation for a limited period of time.

“(c) SPECIFICATION OF CODES.—The Secretary shall determine the appropriate life-safety codes for such clinics that treat patients for needs referred to in subsection (b)(2).

“(d) FUNDING.—

“(1) IN GENERAL.—Subject to paragraph (2), there are authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and

the Federal Supplementary Medical Insurance Trust Fund, such sums as are necessary to conduct the demonstration project under this section.

“(2) BUDGET NEUTRAL IMPLEMENTATION.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration project under this section was not implemented.

“(e) THREE-YEAR PERIOD.—The Secretary shall conduct the demonstration under this section for a 3-year period.

“(f) REPORT.—Not later than the date that is 1 year after the date on which the demonstration project concludes, the Secretary shall submit to Congress a report on the demonstration project, together with such recommendations for legislation or administrative action as the Secretary determines appropriate.

“(g) DEFINITIONS.—In this section, the terms ‘hospital’ and ‘critical access hospital’ have the meanings given such terms in subsections (e) and (mm), respectively, of section 1861 of the Social Security Act (42 U.S.C. 1395x).”

MEDPAC STUDY OF COVERAGE OF SURGICAL FIRST ASSISTING SERVICES OF CERTIFIED REGISTERED NURSE FIRST ASSISTANTS

Pub. L. 108-173, title VI, §643, Dec. 8, 2003, 117 Stat. 2322, provided that:

“(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ‘Commission’) shall conduct a study on the feasibility and advisability of providing for payment under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] for surgical first assisting services furnished by a certified registered nurse first assistant to medicare beneficiaries.

“(b) REPORT.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

“(c) DEFINITIONS.—In this section:

“(1) SURGICAL FIRST ASSISTING SERVICES.—The term ‘surgical first assisting services’ means services consisting of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care (as determined by the Secretary [of Health and Human Services]) furnished by a certified registered nurse first assistant (as defined in paragraph (2)) which the certified registered nurse first assistant is legally authorized to perform by the State in which the services are performed.

“(2) CERTIFIED REGISTERED NURSE FIRST ASSISTANT.—The term ‘certified registered nurse first assistant’ means an individual who—

“(A) is a registered nurse and is licensed to practice nursing in the State in which the surgical first assisting services are performed;

“(B) has completed a minimum of 2,000 hours of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care; and

“(C) is certified as a registered nurse first assistant by an organization recognized by the Secretary.”

STUDIES RELATING TO VISION IMPAIRMENTS

Pub. L. 108-173, title VI, §645, Dec. 8, 2003, 117 Stat. 2323, provided that:

“(a) COVERAGE OF OUTPATIENT VISION SERVICES FURNISHED BY VISION REHABILITATION PROFESSIONALS UNDER PART B.—

“(1) STUDY.—The Secretary [of Health and Human Services] shall conduct a study to determine the feasibility and advisability of providing for payment for

vision rehabilitation services furnished by vision rehabilitation professionals.

“(2) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with recommendations for such legislation or administrative action as the Secretary determines to be appropriate.

“(3) VISION REHABILITATION PROFESSIONAL DEFINED.—In this subsection, the term ‘vision rehabilitation professional’ means an orientation and mobility specialist, a rehabilitation teacher, or a low vision therapist.

“(b) REPORT ON APPROPRIATENESS OF A DEMONSTRATION PROJECT TO TEST FEASIBILITY OF USING PPO NETWORKS TO REDUCE COSTS OF ACQUIRING EYEGLASSES FOR MEDICARE BENEFICIARIES AFTER CATARACT SURGERY.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care preferred provider organization networks to furnish and pay for conventional eyeglasses subsequent to each cataract surgery with insertion of an intraocular lens on behalf of Medicare beneficiaries. In such report, the Secretary shall include an estimate of potential cost savings to the Medicare program through the use of such networks, taking into consideration quality of service and beneficiary access to services offered by vision care preferred provider organization networks.”

DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE

Pub. L. 108-173, title VI, §651, Dec. 8, 2003, 117 Stat. 2332, provided that:

“(a) DEFINITIONS.—In this section:

“(1) CHIROPRACTIC SERVICES.—The term ‘chiropractic services’ has the meaning given that term by the Secretary [of Health and Human Services] for purposes of the demonstration projects, but shall include, at a minimum—

“(A) care for neuromusculoskeletal conditions typical among eligible beneficiaries; and

“(B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided.

“(2) DEMONSTRATION PROJECT.—The term ‘demonstration project’ means a demonstration project established by the Secretary under subsection (b)(1).

“(3) ELIGIBLE BENEFICIARY.—The term ‘eligible beneficiary’ means an individual who is enrolled under part B of the medicare program.

“(4) MEDICARE PROGRAM.—The term ‘medicare program’ means the health benefits program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

“(b) DEMONSTRATION OF COVERAGE OF CHIROPRACTIC SERVICES UNDER MEDICARE.—

“(1) ESTABLISHMENT.—The Secretary shall establish demonstration projects in accordance with the provisions of this section for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the medicare program (in addition to the coverage provided for services consisting of treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Social Security Act (42 U.S.C. 1395x(r)(5))).

“(2) NO PHYSICIAN APPROVAL REQUIRED.—In establishing the demonstration projects, the Secretary shall ensure that an eligible beneficiary who participates in a demonstration project, including an eligible beneficiary who is enrolled for coverage under a Medicare+Choice plan (or, on and after January 1, 2006, under a Medicare Advantage plan), is not required to receive approval from a physician or other health care provider in order to receive a chiropractic service under a demonstration project.

“(3) CONSULTATION.—In establishing the demonstration projects, the Secretary shall consult with chiro-

practitioners, organizations representing chiropractors, eligible beneficiaries, and organizations representing eligible beneficiaries.

“(4) PARTICIPATION.—Any eligible beneficiary may participate in the demonstration projects on a voluntary basis.

“(c) CONDUCT OF DEMONSTRATION PROJECTS.—

“(1) DEMONSTRATION SITES.—

“(A) SELECTION OF DEMONSTRATION SITES.—The Secretary shall conduct demonstration projects at 4 demonstration sites.

“(B) GEOGRAPHIC DIVERSITY.—Of the sites described in subparagraph (A)—

“(i) two shall be in rural areas; and

“(ii) two shall be in urban areas.

“(C) SITES LOCATED IN HPSAS.—At least 1 site described in clause (i) of subparagraph (B) and at least 1 site described in clause (ii) of such subparagraph shall be located in an area that is designated under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) as a health professional shortage area.

“(2) IMPLEMENTATION; DURATION.—

“(A) IMPLEMENTATION.—The Secretary shall not implement the demonstration projects before October 1, 2004.

“(B) DURATION.—The Secretary shall complete the demonstration projects by the date that is 2 years after the date on which the first demonstration project is implemented.

“(d) EVALUATION AND REPORT.—

“(1) EVALUATION.—The Secretary shall conduct an evaluation of the demonstration projects—

“(A) to determine whether eligible beneficiaries who use chiropractic services use a lesser overall amount of items and services for which payment is made under the medicare program than eligible beneficiaries who do not use such services;

“(B) to determine the cost of providing payment for chiropractic services under the medicare program;

“(C) to determine the satisfaction of eligible beneficiaries participating in the demonstration projects and the quality of care received by such beneficiaries; and

“(D) to evaluate such other matters as the Secretary determines is appropriate.

“(2) REPORT.—Not later than the date that is 1 year after the date on which the demonstration projects conclude, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) together with such recommendations for legislative or administrative action as the Secretary determines is appropriate.

“(e) WAIVER OF MEDICARE REQUIREMENTS.—The Secretary shall waive compliance with such requirements of the medicare program to the extent and for the period the Secretary finds necessary to conduct the demonstration projects.

“(f) FUNDING.—

“(1) DEMONSTRATION PROJECTS.—

“(A) IN GENERAL.—Subject to subparagraph (B) and paragraph (2), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the demonstration projects under this section.

“(B) LIMITATION.—In conducting the demonstration projects under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.

“(2) EVALUATION AND REPORT.—There are authorized to be appropriated such sums as are necessary for the purpose of developing and submitting the report to Congress under subsection (d).”

DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND

Pub. L. 108-173, title VII, §702, Dec. 8, 2003, 117 Stat. 2335, provided that:

“(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall conduct a 2-year demonstration project under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be homebound for purposes of receiving home health services under the medicare program.

“(b) MEDICARE BENEFICIARY DESCRIBED.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if—

“(1) the beneficiary has been certified by one physician as an individual who has a permanent and severe, disabling condition that is not expected to improve;

“(2) the beneficiary is dependent upon assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the beneficiary's life;

“(3) the beneficiary requires skilled nursing services for the rest of the beneficiary's life and the skilled nursing is more than medication management;

“(4) an attendant is required to visit the beneficiary on a daily basis to monitor and treat the beneficiary's medical condition or to assist the beneficiary with activities of daily living;

“(5) the beneficiary requires technological assistance or the assistance of another person to leave the home; and

“(6) the beneficiary does not regularly work in a paid position full-time or part-time outside the home.

“(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

“(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000.

“(e) DATA.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

“(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e). The report shall include the following:

“(1) An examination of whether the provision of home health services to medicare beneficiaries under the project has had any of the following effects:

“(A) Has adversely affected the provision of home health services under the medicare program.

“(B) Has directly caused an increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification.

“(2) The specific data evidencing the amount of any increase in expenditures that is directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program.

“(3) Specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional costs to the medicare program.

“(g) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

“(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XI or title XVIII of the Social Security Act [42 U.S.C. 1395 et seq., 1301 et seq.] for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program.

“(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

“(j) DEFINITIONS.—In this section:

“(1) MEDICARE BENEFICIARY.—The term ‘medicare beneficiary’ means an individual who is enrolled under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.].

“(2) HOME HEALTH SERVICES.—The term ‘home health services’ has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

“(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ‘activities of daily living’ means eating, toileting, transferring, bathing, and dressing.”

INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS

Pub. L. 108-173, title IX, § 926(a), Dec. 8, 2003, 117 Stat. 2396, provided that: “The Secretary [of Health and Human Services] shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.”

IMPLEMENTATION OF AMENDMENTS BY PUB. L. 105-277

Pub. L. 105-277, div. J, title V, § 5101(i), Oct. 21, 1998, 112 Stat. 2681-916, provided that:

“(1) IN GENERAL.—The Secretary of Health and Human Services shall promptly issue (without regard to chapter 8 of title 5, United States Code) such regulations or program memoranda as may be necessary to effect the amendments made by this section [amending this section, sections 1395r and 1395fff of this title, and provisions set out as notes under section 1395fff of this title] for cost reporting periods beginning during fiscal year 1999.

“(2) USE OF PAYMENT AMOUNTS AND LIMITS FROM PUBLISHED TABLES.—

“(A) PER BENEFICIARY LIMITS.—In effecting the amendments made by subsection (a) [amending this section] for cost reporting periods beginning in fiscal year 1999, the ‘median’ referred to in section 1861(v)(1)(L)(vi)(I) of the Social Security Act [42 U.S.C. 1395x(v)(1)(L)(vi)(I)] for such periods shall be the national standardized per beneficiary limitation specified in Table 3C published in the Federal Register on August 11, 1998 (63 FR 42926) and the ‘standardized regional average of such costs’ referred to in section 1861(v)(1)(L)(v)(I) of such Act [42 U.S.C. 1395x(v)(1)(L)(v)(I)] for a census division shall be the sum of the labor and nonlabor components of the standardized per beneficiary limitation for that census division specified in Table 3B published in the Federal Register on that date (63 FR 42926) (or in Table 3D as so published with respect to Puerto Rico and Guam), and adjusted to reflect variations in wages among different geographic areas as specified in Tables 4a and 4b published in the Federal Register on that date (63 FR 42926-42933).

“(B) PER VISIT LIMITS.—In effecting the amendments made by subsection (b) [amending this section] for cost reporting periods beginning in fiscal year

1999, the limits determined under section 1861(v)(1)(L)(i)(V) of such Act [42 U.S.C. 1395x(v)(1)(L)(i)(V)] for cost reporting periods beginning during such fiscal year shall be equal to the per visit limits as specified in Table 3A published in the Federal Register on August 11, 1998 (63 FR 42925) and as subsequently corrected, multiplied by ¹⁰⁶/₁₀₅, and adjusted to reflect variations in wages among different geographic areas as specified in Tables 4a and 4b published in the Federal Register on August 11, 1998 (63 FR 42926-42933).”

STUDY ON EXPANSION OF MEDICAL NUTRITION THERAPY SERVICES BENEFIT

Pub. L. 106-554, § 1(a)(6) [title I, § 105(f)], Dec. 21, 2000, 114 Stat. 2763, 2763A-472, provided that: “Not later than July 1, 2003, the Secretary of Health and Human Services shall submit to Congress a report that contains recommendations with respect to the expansion to other medicare beneficiary populations of the medical nutrition therapy services benefit (furnished under the amendments made by this section [amending this section and sections 1395l and 1395u of this title]).”

STUDY ON MEDICARE COVERAGE OF ROUTINE THYROID SCREENING

Pub. L. 106-554, § 1(a)(6) [title I, § 123], Dec. 21, 2000, 114 Stat. 2763, 2763A-478, provided that:

“(a) STUDY.—The Secretary of Health and Human Services shall request the National Academy of Sciences, and as appropriate in conjunction with the United States Preventive Services Task Force, to conduct a study on the addition of coverage of routine thyroid screening using a thyroid stimulating hormone test as a preventive benefit provided to medicare beneficiaries under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for some or all medicare beneficiaries. In conducting the study, the Academy shall consider the short-term and long-term benefits, and costs to the medicare program, of such addition.

“(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall submit a report on the findings of the study conducted under subsection (a) to the Committee on Ways and Means and the Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate.”

GAO STUDY ON COVERAGE OF SURGICAL FIRST ASSISTING SERVICES OF CERTIFIED REGISTERED NURSE FIRST ASSISTANTS

Pub. L. 106-554, § 1(a)(6) [title IV, § 433], Dec. 21, 2000, 114 Stat. 2763, 2763A-526, provided that:

“(a) STUDY.—The Comptroller General of the United States shall conduct a study on the effect on the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] and on medicare beneficiaries of coverage under the program of surgical first assisting services of certified registered nurse first assistants. The Comptroller General shall consider the following when conducting the study:

“(1) Any impact on the quality of care furnished to medicare beneficiaries by reason of such coverage.

“(2) Appropriate education and training requirements for certified registered nurse first assistants who furnish such first assisting services.

“(3) Appropriate rates of payment under the program to such certified registered nurse first assistants for furnishing such services, taking into account the costs of compensation, overhead, and supervision attributable to certified registered nurse first assistants.

“(b) REPORT.—Not later than 1 year after the date of the enactment of this Act [Dec. 21, 2000], the Comptrol-

ler General shall submit to Congress a report on the study conducted under subsection (a).”

MEDPAC STUDY AND REPORT ON MEDICARE COVERAGE OF SERVICES PROVIDED BY CERTAIN NONPHYSICIAN PROVIDERS

Pub. L. 106-554, §1(a)(6) [title IV, §435], Dec. 21, 2000, 114 Stat. 2763, 2763A-527, provided that:

“(a) STUDY.—

“(1) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study to determine the appropriateness of providing coverage under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for services provided by a—

“(A) surgical technologist;

“(B) marriage counselor;

“(C) marriage and family therapist;

“(D) pastoral care counselor; and

“(E) licensed professional counselor of mental health.

“(2) COSTS TO PROGRAM.—The study shall consider the short-term and long-term benefits, and costs to the medicare program, of providing the coverage described in paragraph (1).

“(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study conducted under subsection (a), together with any recommendations for legislation that the Commission determines to be appropriate as a result of such study.”

DEVELOPMENT OF PATIENT ASSESSMENT INSTRUMENTS

Pub. L. 106-554, §1(a)(6) [title V, §545], Dec. 21, 2000, 114 Stat. 2763, 2763A-551, provided that:

“(a) DEVELOPMENT.—

“(1) IN GENERAL.—Not later than January 1, 2005, the Secretary of Health and Human Services shall submit to the Committee on Ways and Means and the Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate a report on the development of standard instruments for the assessment of the health and functional status of patients, for whom items and services described in subsection (b) are furnished, and include in the report a recommendation on the use of such standard instruments for payment purposes.

“(2) DESIGN FOR COMPARISON OF COMMON ELEMENTS.—The Secretary shall design such standard instruments in a manner such that—

“(A) elements that are common to the items and services described in subsection (b) may be readily comparable and are statistically compatible;

“(B) only elements necessary to meet program objectives are collected; and

“(C) the standard instruments supersede any other assessment instrument used before that date.

“(3) CONSULTATION.—In developing an assessment instrument under paragraph (1), the Secretary shall consult with the Medicare Payment Advisory Commission, the Agency for Healthcare Research and Quality, and qualified organizations representing providers of services and suppliers under title XVIII [42 U.S.C. 1395 et seq.].

“(b) DESCRIPTION OF SERVICES.—For purposes of subsection (a), items and services described in this subsection are those items and services furnished to individuals entitled to benefits under part A, or enrolled under part B, or both of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] for which payment is made under such title [42 U.S.C. 1395 et seq.], and include the following:

“(1) Inpatient and outpatient hospital services.

“(2) Inpatient and outpatient rehabilitation services.

“(3) Covered skilled nursing facility services.

“(4) Home health services.

“(5) Physical or occupational therapy or speech-language pathology services.

“(6) Items and services furnished to such individuals determined to have end stage renal disease.

“(7) Partial hospitalization services and other mental health services.

“(8) Any other service for which payment is made under such title as the Secretary determines to be appropriate.”

CONFORMING REFERENCES TO PREVIOUS PART C

Pub. L. 105-33, title IV, §4002(f)(1), Aug. 5, 1997, 111 Stat. 329, provided that: “Any reference in law (in effect before the date of the enactment of this Act [Aug. 5, 1997]) to part C of title XVIII of the Social Security Act [42 U.S.C. 1395w-21 et seq.] is deemed a reference to part D of such title [42 U.S.C. 1395w-101 et seq.] (as in effect after such date).”

DEADLINE FOR PUBLICATION OF DETERMINATION ON COVERAGE OF SCREENING BARIUM ENEMA

Pub. L. 105-33, title IV, §4104(a)(2), Aug. 5, 1997, 111 Stat. 363, provided that: “Not later than the earlier of the date that is January 1, 1998, or 90 days after the date of the enactment of this Act [Aug. 5, 1997], the Secretary of Health and Human Services shall publish notice in the Federal Register with respect to the determination under paragraph (1)(D) of section 1861(pp) of the Social Security Act (42 U.S.C. 1395x(pp)), as added by paragraph (1), on the coverage of a screening barium enema as a colorectal cancer screening test under such section.”

ESTABLISHMENT OF OUTCOME MEASURES FOR BENEFICIARIES WITH DIABETES

Pub. L. 105-33, title IV, §4105(c), Aug. 5, 1997, 111 Stat. 367, provided that:

“(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with appropriate organizations, shall establish outcome measures, including glycosylated hemoglobin (past 90-day average blood sugar levels), for purposes of evaluating the improvement of the health status of medicare beneficiaries with diabetes mellitus.

“(2) RECOMMENDATIONS FOR MODIFICATIONS TO SCREENING BENEFITS.—Taking into account information on the health status of medicare beneficiaries with diabetes mellitus as measured under the outcome measures established under paragraph (1), the Secretary shall from time to time submit recommendations to Congress regarding modifications to the coverage of services for such beneficiaries under the medicare program.”

VACCINES OUTREACH EXPANSION

Pub. L. 105-33, title IV, §4107, Aug. 5, 1997, 111 Stat. 368, provided that:

“(a) EXTENSION OF INFLUENZA AND PNEUMOCOCCAL VACCINATION CAMPAIGN.—In order to increase utilization of pneumococcal and influenza vaccines in medicare beneficiaries, the Influenza and Pneumococcal Vaccination Campaign carried out by the Health Care Financing Administration in conjunction with the Centers for Disease Control and Prevention and the National Coalition for Adult Immunization, is extended until the end of fiscal year 2002.

“(b) AUTHORIZATION OF APPROPRIATION.—There are hereby authorized to be appropriated for each of fiscal years 1998 through 2002, \$8,000,000 for the Campaign described in subsection (a). Of the amount so authorized to be appropriated in each fiscal year, 60 percent of the amount so appropriated shall be payable from the Federal Hospital Insurance Trust Fund, and 40 percent shall be payable from the Federal Supplementary Medical Insurance Trust Fund.”

STUDY ON PREVENTIVE AND ENHANCED BENEFITS

Pub. L. 105-33, title IV, §4108, Aug. 5, 1997, 111 Stat. 369, directed the Secretary of Health and Human Services to request the National Academy of Sciences to analyze the expansion or modification of preventive or other benefits provided to medicare beneficiaries under

this subchapter, and not later than 2 years after Aug. 5, 1997, to submit a report on the findings of the analysis to Congress.

UTILIZATION GUIDELINES

Pub. L. 105-33, title IV, § 4513(c), Aug. 5, 1997, 111 Stat. 444, provided that: "The Secretary of Health and Human Services shall develop and implement utilization guidelines relating to the coverage of chiropractic services under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] in cases in which a subluxation has not been demonstrated by X-ray to exist."

AUTHORIZING PAYMENT FOR PARAMEDIC INTERCEPT SERVICE PROVIDERS IN RURAL COMMUNITIES

Pub. L. 105-33, title IV, § 4531(c), Aug. 5, 1997, 111 Stat. 452, as amended by Pub. L. 106-113, div. B, § 1000(a)(6) [title IV, § 412(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A-377, provided that: "In promulgating regulations to carry out section 1861(s)(7) of the Social Security Act (42 U.S.C. 1395x(s)(7)) with respect to the coverage of ambulance service, the Secretary of Health and Human Services may include coverage of advanced life support services (in this subsection referred to as 'ALS intercept services') provided by a paramedic intercept service provider in a rural area if the following conditions are met:

"(1) The ALS intercept services are provided under a contract with one or more volunteer ambulance services and are medically necessary based on the health condition of the individual being transported.

"(2) The volunteer ambulance service involved—

"(A) is certified as qualified to provide ambulance service for purposes of such section,

"(B) provides only basic life support services at the time of the intercept, and

"(C) is prohibited by State law from billing for any services.

"(3) The entity supplying the ALS intercept services—

"(A) is certified as qualified to provide such services under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and

"(B) bills all recipients who receive ALS intercept services from the entity, regardless of whether or not such recipients are medicare beneficiaries.

For purposes of this subsection, an area shall be treated as a rural area if it is designated as a rural area by any law or regulation of the State or if it is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725))."

[Pub. L. 106-113, div. B, § 1000(a)(6) [title IV, § 412(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A-377, provided that: "The amendment made by subsection (a) [amending section 4531(c) of Pub. L. 105-33, set out above] takes effect on January 1, 2000, and applies to ALS intercept services furnished on or after such date."]

NO EXCEPTIONS PERMITTED BASED ON AMENDMENT TO SUBSECTION (v)(1)(L)

Pub. L. 105-33, title IV, § 4601(b), Aug. 5, 1997, 111 Stat. 466, provided that: "The Secretary of Health and Human Services shall not consider the amendment made by subsection (a) [amending this section] in making any exemptions and exceptions pursuant to section 1861(v)(1)(L)(ii) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(ii))."

STUDY ON DEFINITION OF HOMEBOUND

Pub. L. 105-33, title IV, § 4613, Aug. 5, 1997, 111 Stat. 474, provided that:

"(a) STUDY.—The Secretary of Health and Human Services shall conduct a study of the criteria that should be applied, and the method of applying such criteria, in the determination of whether an individual is homebound for purposes of qualifying for receipt of

benefits for home health services under the medicare program. Such criteria shall include the extent and circumstances under which a person may be absent from the home but nonetheless qualify.

"(b) REPORT.—Not later than October 1, 1998, the Secretary shall submit a report to Congress on the study conducted under subsection (a). The report shall include specific recommendations on such criteria and methods."

REVISIONS OF COVERAGE FOR IMMUNOSUPPRESSIVE DRUG THERAPY

Pub. L. 103-432, title I, § 160(c), Oct. 31, 1994, 108 Stat. 4443, provided that: "The Secretary of Health and Human Services may administer section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)) in a manner such that the months of coverage of drugs described in such section are provided consecutively, so long as the total number of months of coverage provided is the same as the number of months described in such section."

FREEZE IN PER VISIT COST LIMITS FOR HOME HEALTH SERVICES

Pub. L. 103-66, title XIII, § 13564(a)(1), Aug. 10, 1993, 107 Stat. 607, provided that: "The Secretary of Health and Human Services shall not provide for any change in the per visit cost limits for home health services under section 1861(v)(1)(L) of such Act [42 U.S.C. 1395x(v)(1)(L)] for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, except as may be necessary to take into account the amendment made by subsection (b)(1) [amending this section]. The effect of the preceding sentence shall not be considered by the Secretary in making adjustments pursuant to section 1861(v)(1)(L)(ii) of such Act to the payment limits for such services during such cost reporting periods."

STUDY AND REPORT ON EFFECTS OF COVERAGE OF OSTEOPOROSIS DRUGS

Pub. L. 101-508, title IV, § 4156(b), Nov. 5, 1990, 104 Stat. 1388-88, directed Secretary of Health and Human Services to conduct a study analyzing effects of coverage of osteoporosis drugs under part B of this subchapter on health of individuals enrolled under such part and utilization of inpatient hospital and extended care services by such individuals, and, by not later than Oct. 1, 1994, to submit a report to Congress on such study, which was to include recommendations regarding expansion of coverage under the medicare program of items and services for individuals with postmenopausal osteoporosis as the Secretary considered appropriate.

PRODUCTIVITY SCREENING GUIDELINES APPLICATION TO STAFF IN RURAL HEALTH CLINICS

Pub. L. 101-508, title IV, § 4161(b)(3), Nov. 5, 1990, 104 Stat. 1388-95, provided that: "In employing any screening guideline in determining the productivity of physicians, physician assistants, nurse practitioners, and certified nurse-midwives in a rural health clinic, the Secretary of Health and Human Services shall provide that the guideline shall take into account the combined services of such staff (and not merely the service within each class of practitioner)."

DEVELOPMENT OF PROSPECTIVE PAYMENT SYSTEM FOR HOME HEALTH SERVICES

Pub. L. 101-508, title IV, § 4207(c), formerly § 4027(c), Nov. 5, 1990, 104 Stat. 1388-119, as renumbered and amended by Pub. L. 103-432, title I, § 160(d)(4), (9), Oct. 31, 1994, 108 Stat. 4444; Pub. L. 105-362, title VI, § 601(b)(2), Nov. 10, 1998, 112 Stat. 3286, directed Secretary of Health and Human Services to develop a proposal to modify the current system under which payment is made for home health services under this subchapter or a proposal to replace such system with a system under which such payments would be made on the basis of prospectively determined rates, with Sec-

retary to submit to Congress by not later than Apr. 1, 1993, the research findings upon which the proposal was to be based, and directed Prospective Payment Assessment Commission to submit to Congress by not later than Mar. 1, 1994, an analysis of and comments on the proposal.

APPLICATION OF BUDGET-NEUTRAL BASIS

Pub. L. 101-508, title IV, §4207(d)(2), formerly §4027(d)(2), Nov. 5, 1990, 104 Stat. 1388-120, as renumbered by Pub. L. 103-432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that: "In updating the wage index for establishing limits under section 1861(v)(1)(L)(iii) of the Social Security Act [42 U.S.C. 1395x(v)(1)(L)(iii)], the Secretary shall ensure that aggregate payments to home health agencies under title XVIII of such Act [42 U.S.C. 1395 et seq.] will be no greater or lesser than such payments would have been without regard to such update."

TRANSITION PROVISIONS FOR DETERMINING REASONABLE COSTS FOR HOME HEALTH AGENCY SERVICES

Pub. L. 101-508, title IV, §4207(d)(3), formerly §4027(d)(3), Nov. 5, 1990, 104 Stat. 1388-121, as renumbered by Pub. L. 103-432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that, notwithstanding subsec. (v)(1)(L)(iii) of this section, the Secretary of Health and Human Services was to, in determining the limits of reasonable costs under this subchapter with respect to services furnished by a home health agency, utilize a wage index equal to (1) for cost reporting periods beginning on or after July 1, 1991, and on or before June 30, 1992, a combined area wage index consisting of 67 percent of the area wage index applicable to such home health agency, determined using the survey of the 1982 wages and wage-related costs of hospitals in the United States, and 33 percent of the area wage index applicable to hospitals located in the geographic area in which the home health agency was located, determined using the survey of the 1988 wages and wage-related costs of hospitals in the United States, and (2) for cost reporting periods beginning on or after July 1, 1992, and on or before June 30, 1993, a combined area wage index consisting of 33 percent of the area wage index applicable to such home health agency, determined using the survey of the 1982 wages and wage-related costs of hospitals in the United States, and 67 percent of the area wage index applicable to hospitals located in the geographic area in which the home health agency was located, determined using the survey of the 1988 wages and wage-related costs of hospitals in the United States.

PERMITTING DENTIST TO SERVE AS HOSPITAL MEDICAL DIRECTOR

Pub. L. 101-239, title VI, §6025, Dec. 19, 1989, 103 Stat. 2167, provided that: "Notwithstanding the requirement that the responsibility for organization and conduct of the medical staff of an institution be assigned only to a doctor of medicine or osteopathy in order for the institution to participate as a hospital under the medicare program, an institution that has a doctor of dental surgery or of dental medicine serving as its medical director shall be considered to meet such requirement if the laws of the State in which the institution is located permit a doctor of dental surgery or of dental medicine to serve as the medical staff director of a hospital."

RECOGNITION OF COSTS OF CERTAIN HOSPITAL-BASED NURSING SCHOOLS

Pub. L. 101-239, title VI, §6205(a)(1)(A), Dec. 19, 1989, 103 Stat. 2243, provided that: "The reasonable costs incurred by a hospital in training students of a hospital-based nursing school shall be allowable as reasonable costs under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] and reimbursed under such title on the same basis as if they were allowable direct costs of a hospital-operated educational program (other than an approved graduate medical education program) if, before June 15, 1989, and thereafter, the hospital dem-

onstrates that for each year, it incurs at least 50 percent of the costs of training nursing students at such school, the nursing school and the hospital share some common board members, and all instruction is provided at the hospital or, if in another building, a building on the immediate grounds of the hospital."

[Pub. L. 101-239, title VI, §6205(a)(2), Dec. 19, 1989, 103 Stat. 2243, provided that: "Paragraph (1)(A) [set out above] shall apply with respect to cost reporting periods beginning on or after the date of the enactment of this Act [Dec. 19, 1989] and on or before the date on which the Secretary issues regulations pursuant to subsection (b)(2)(A) [set out as a note under section 1395ww of this title]."]

DISSEMINATION OF RURAL HEALTH CLINIC INFORMATION

Pub. L. 101-239, title VI, §6213(e), Dec. 19, 1989, 103 Stat. 2251, directed Secretary of Health and Human Services, not later than 60 days after Dec. 19, 1989, in consultation with the Director of the Office of Rural Health Policy, to disseminate to health care facilities and to the chief executive officer, chief health officer, and chief human services officer of each State, applications and other necessary information to enable such a facility to apply for designation as a rural health clinic for the purposes of this subchapter and subchapter XIX of this chapter.

TREATMENT OF CERTAIN FACILITIES AS RURAL HEALTH CLINICS

Pub. L. 101-239, title VI, §6213(f), Dec. 19, 1989, 103 Stat. 2251, provided that: "The Secretary of Health and Human Services shall not deny certification of a facility as a rural health clinic under section 1861(aa)(2) of the Social Security Act [42 U.S.C. 1395x(aa)(2)] if the facility is located on an island and would otherwise be qualified to be certified as such a facility but for the requirement that the services of a physician assistant or nurse practitioner be provided in the facility."

CONTINUED USE OF HOME HEALTH WAGE INDEX IN EFFECT PRIOR TO JULY 1, 1989, UNTIL AFTER JULY 1, 1991

Pub. L. 101-239, title VI, §6222, Dec. 19, 1989, 103 Stat. 2256, provided that: "Notwithstanding the requirement of section 1861(v)(1)(L)(iii) of the Social Security Act [42 U.S.C. 1395x(v)(1)(L)(iii)], the Secretary of Health and Human Services shall, in determining the limits of reasonable costs under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] with respect to services furnished by home health agencies, continue to utilize the wage index that was in effect for cost reporting periods beginning before July 1, 1989, until cost reporting periods beginning on or after July 1, 1991."

PAYMENT FOR MEDICAL ESCORT OR MEDICAL ATTENDANT ON COMMERCIAL AIRLINER ALLOWED

Pub. L. 100-647, title VIII, §8427, Nov. 10, 1988, 102 Stat. 3803, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall provide that in cases where (as of the date of the enactment of this Act [Nov. 10, 1988]) transportation on a commercial airliner is covered under section 1861(s)(7) of the Social Security Act [42 U.S.C. 1395x(s)(7)], the Secretary shall also provide for payment for medically necessary services of a medical escort or medical attendant.

"(b) EFFECTIVE PERIOD.—Subsection (a) shall apply to payment for services furnished during the 5-year period beginning on July 1, 1989."

SKILLED NURSING FACILITY; ACCESS AND VISITATION RIGHTS

Pub. L. 100-360, title IV, §411(i)(2)(E), July 1, 1988, 102 Stat. 802, provided that: "Effective as of the date of the enactment of this Act [July 1, 1988] and until the effective date of section 1819(c) of such Act [see Effective Date note set out under section 1395i-3 of this title], section 1861(j) of the Social Security Act [42 U.S.C.

1395x(j)] is deemed to include the requirement described in section 1819(c)(3)(A) of such Act [42 U.S.C. 1395i-3(c)(3)(A)] (as added by section 4201(a)(3) of OBRA).”

MORATORIUM ON PRIOR AUTHORIZATION FOR HOME HEALTH AND POST-HOSPITAL EXTENDED CARE SERVICES

Pub. L. 100-203, title IV, §4039(e), Dec. 22, 1987, 101 Stat. 1330-82, provided that: “The Secretary of Health and Human Services shall not implement any voluntary or mandatory program of prior authorization for home health services, extended care services, or post-hospital extended care services under part A or B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] at any time prior to six months after the date on which the Congress receives the report required under section 9305(k)(4) of the Omnibus Budget Reconciliation Act of 1986 [section 9305(k)(4) of Pub. L. 99-509, set out below].”

DELAY IN PUBLISHING REGULATIONS WITH RESPECT TO DEEMING STATUS OF ENTITIES

Pub. L. 100-203, title IV, §4039(f), Dec. 22, 1987, 101 Stat. 1330-82, provided that: “The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) shall not deem any entity to be a provider of services (as defined in section 1861(u) of the Social Security Act [42 U.S.C. 1395x(u)]) for purposes of title XVIII of such Act [42 U.S.C. 1395 et seq.]—

“(1) on any date prior to 6 months after the date on which the Secretary has published a proposed rule with respect to the deeming of the entity, and

“(2) until the Secretary publishes a final rule with respect to the deeming of the entity.”

DEVELOPMENT OF UNIFORM NEEDS ASSESSMENT INSTRUMENT

Pub. L. 99-509, title IX, §9305(h), Oct. 21, 1986, 100 Stat. 2035, directed Secretary of Health and Human Services to develop a uniform needs assessment instrument that could be used by discharge planners, hospitals, nursing facilities, other health care providers, and fiscal intermediaries in evaluating individual’s need for post-hospital extended care services, home health services, and long-term care services of health-related or supportive nature, and further provided for creation of advisory panel to assist Secretary and for a report to Congress not later than Jan. 1, 1989.

PRIOR AND CONCURRENT AUTHORIZATION DEMONSTRATION PROJECT

Pub. L. 99-509, title IX, §9305(k), Oct. 21, 1986, 100 Stat. 2035, directed Secretary of Health and Human Services to conduct a demonstration program concerning prior and concurrent authorization for post-hospital extended care services and home health services furnished under part A or part B of this subchapter, which was to include at least four projects and was to be initiated by not later than Jan. 1, 1987, under which the Secretary was to monitor the acceptance of individuals entitled to benefits under this subchapter by providers to ensure that the placement of such individuals was not delayed until the results of prior and concurrent review were known, and further directed Secretary to evaluate the demonstration program and report to Congress on such evaluation no later than Feb. 1, 1989.

CONSIDERATIONS IN ESTABLISHING LIMITS ON PAYMENT FOR HOME HEALTH SERVICES

Pub. L. 99-509, title IX, §9315(b), Oct. 21, 1986, 100 Stat. 2006, provided that: “In establishing limitations under section 1861(v)(1)(L) of the Social Security Act [42 U.S.C. 1395x(v)(1)(L)] on payment for home health services for cost reporting periods beginning on or after July 1, 1986, the Secretary of Health and Human Services shall—

“(1) base such limitations on the most recent data available, which data may be for cost reporting periods beginning no earlier than October 1, 1983; and

“(2) take into account the changes in costs of home health agencies for billing and verification procedures that result from the Secretary’s changing the requirements for such procedures, to the extent the changes in costs are not reflected in such data.

Paragraph (2) shall apply to changes in requirements effected before, on, or after July 1, 1986.”

COMPTROLLER GENERAL STUDY AND REPORT ON COST LIMITS FOR HOME HEALTH SERVICES

Pub. L. 99-509, title IX, §9315(c), Oct. 21, 1986, 100 Stat. 2006, directed Comptroller General to study and report to Congress, not later than Feb. 1, 1988, on appropriateness and impact on medicare beneficiaries of applying the per visit cost limits for home health services under subsec. (v)(1)(L) of this section on a discipline-specific basis, rather than on an aggregate basis, for all home health services furnished by an agency, and appropriateness of the percentage limits so established.

REDUCTION IN PAYMENT TO AVOID DUPLICATE PAYMENT FOR SERVICES OF PHYSICIAN ASSISTANTS

Pub. L. 99-509, title IX, §9338(d), Oct. 21, 1986, 100 Stat. 2035, directed Secretary of Health and Human Services to reduce the amount of payments otherwise made to hospitals and skilled nursing facilities under this subchapter to eliminate estimated duplicate payments for historical or current costs attributable to services described in section 1395x(s)(2)(K) of this title, prior to repeal by Pub. L. 101-508, title IV, §4002(f), Nov. 5, 1990, 104 Stat. 1388-36, effective as if included in the enactment of Pub. L. 99-509.

STUDY AND REPORT ON PAYMENTS FOR PHYSICIAN ASSISTANTS

Pub. L. 99-509, title IX, §9338(e), Oct. 21, 1986, 100 Stat. 2035, directed Secretary to report to Congress, by Apr. 1, 1988, concerning adjustments to amount of payment made, under part B for services described in subsec. (s)(2)(K) of this section, to ensure that amount of such payments reflects approximate cost of furnishing the services, taking into account compensation costs and overhead and supervision costs attributable to physician assistants.

COST LIMITS FOR ROUTINE SERVICES FOR URBAN AND RURAL HOSPITAL-BASED SKILLED NURSING FACILITIES; COST REPORTING PERIODS BEGINNING ON OR AFTER OCTOBER 1, 1982, AND PRIOR TO JULY 1, 1984

Pub. L. 98-369, div. B, title III, §2319(d), July 18, 1984, 98 Stat. 1083, provided that: “Notwithstanding limits on the cost of skilled nursing facilities which may have been issued under section 1861(v) of the Social Security Act [42 U.S.C. 1395x(v)] prior to the date of the enactment of this Act [July 18, 1984], in the case of cost reporting periods beginning on or after October 1, 1982, and prior to July 1, 1984, the cost limits for routine services for urban and rural hospital-based skilled nursing facilities shall be 112 percent of the mean of the respective routine costs for urban and rural hospital-based skilled nursing facilities.”

STUDY AND REPORT RELATING TO REQUIREMENTS THAT CORE SERVICES BE FURNISHED DIRECTLY BY HOSPICES

Pub. L. 98-369, div. B, title III, §2343(d), July 18, 1984, 98 Stat. 1095, directed Secretary of Health and Human Services to conduct a study of necessity and appropriateness of requirements that certain “core” services be furnished directly by a hospice, as required under subsec. (dd)(2)(A)(ii)(I) of this section and report results of such study to Congress with the report required under section 122(i)(1) [122(j)(1)] of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-248), set out as a note under section 1395f of this title.

REPORT ON EFFECT OF 1982 AMENDMENT ON HOSPITAL-BASED SKILLED NURSING FACILITIES

Pub. L. 98-21, title VI, §605(b), Apr. 20, 1983, 97 Stat. 169, directed Secretary of Health and Human Services,

prior to Dec. 31, 1983, to complete a study and report to Congress with respect to (1) effect which implementation of section 102 of the Tax Equity and Fiscal Responsibility Act of 1982, amending this section, would have on hospital-based skilled nursing facilities, given the differences (if any) in patient populations served by such facilities and by community-based skilled nursing facilities and (2) impact on skilled nursing facilities of hospital prospective payment systems, and recommendations concerning payment of skilled nursing facilities.

Pub. L. 98-369, div. B, title III, §2319(e), July 18, 1984, 98 Stat. 1083, directed Secretary of Health and Human Services to submit to Congress, prior to Dec. 1, 1984, the report required under section 605(b) of the Social Security Amendments of 1983 (Pub. L. 87-21), set out above.

ELIMINATION OF PRIVATE ROOM SUBSIDY

Pub. L. 97-248, title I, §111, Sept. 3, 1982, 96 Stat. 340, provided that:

“(a) The Secretary of Health and Human Services shall, pursuant to section 1861(v)(2) of the Social Security Act [42 U.S.C. 1395x(v)(2)], not allow as a reasonable cost the estimated amount by which the costs incurred by a hospital or skilled nursing facility for non-medically necessary private accommodations for medicare beneficiaries exceeds the costs which would have been incurred by such hospital or facility for semi-private accommodations.

“(b) The Secretary of Health and Human Services shall first issue such final regulations (whether on an interim or other basis) as may be necessary to implement subsection (a) by October 1, 1982. If such regulations are promulgated on an interim final basis, the Secretary shall take such steps as may be necessary to provide opportunity for public comment, and appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than January 31, 1983.”

REGULATIONS REGARDING ACCESS TO BOOKS AND RECORDS

Pub. L. 96-499, title IX, §952(b), as added by Pub. L. 97-248, title I, §127(2), Sept. 3, 1982, 96 Stat. 366, provided that: “Unless the Secretary of Health and Human Services first publishes final regulations prescribing the criteria and procedures described in the last sentence of section 1861(v)(1)(I) of the Social Security Act [42 U.S.C. 1395x(v)(1)(I)] by January 1, 1983, after providing a period of not less than 60 days for public comment on proposed regulations, the amendment made by subsection (a) [amending this section] shall only apply to books, documents, and records relating to services furnished (pursuant to contract or subcontract) on or after the date on which final regulations of the Secretary are first published.”

COMPLIANCE WITH THE LIFE SAFETY CODE OR STATE FIRE AND SAFETY CODE

Pub. L. 96-499, title IX, §915(b), Dec. 5, 1980, 94 Stat. 2623, provided that: “Any institution (or part of an institution) which complied with the requirements of section 1861(j)(13) of the Social Security Act [42 U.S.C. 1395x(j)(13)] on the day before the date of the enactment of this Act [Dec. 5, 1980] shall, so long as such compliance is maintained (either by meeting the applicable provisions of the Life Safety Code (21st edition, 1967, or 23d edition, 1973), with or without waivers of specific provisions, or by meeting the applicable provisions of a fire and safety code imposed by State law as provided for in such section 1861(j)(13)), be considered (for purposes of titles XVIII or XIX of such Act [42 U.S.C. 1395 et seq., 1396 et seq.]) to be in compliance with the requirements of such section 1861(j)(13), as it is amended by subsection (a) of this section.”

Pub. L. 94-182, title I, §106(c), Dec. 31, 1975, 89 Stat. 1052, provided that: “Any institution (or part of an institution) which complied with the requirements of section 1861(j)(13) of the Social Security Act [42 U.S.C.

1395x(j)(13)] on the day preceding the first day referred to in subsection (b) [enacting provisions set out as a note under this section] shall, so long as such compliance is maintained (either by meeting the applicable provisions of the Life Safety Code (21st edition, 1967), with or without waivers of specific provisions, or by meeting the applicable provisions of a fire and safety code imposed by State law as provided for in such section 1861(j)(13)), be considered (for purposes of titles XVIII and XIX of such Act) [42 U.S.C. 1395 et seq., 1396 et seq.] to be in compliance with the requirements of such section 1861(j)(13), as it is amended by subsection (a) of this section.”

PRIVATE, NONPROFIT HEALTH CARE CLINICS QUALIFYING, AS OF JULY 1, 1977, AS RURAL HEALTH CLINICS

Pub. L. 95-210, §1(e), Dec. 13, 1977, 91 Stat. 1487, provided that: “Any private, nonprofit health care clinic that—

“(1) on July 1, 1977, was operating and located in an area which on that date (A) was not an urbanized area (as defined by the Bureau of the Census) and (B) had a supply of physicians insufficient to meet the needs of the area (as determined by the Secretary), and

“(2) meets the definition of a rural health clinic under section 1861(aa)(2) [42 U.S.C. 1395x(aa)(2)] or section 1905(l) of the Social Security Act [42 U.S.C. 1396d(l)], except for clause (i) of section 1861(aa)(2) [42 U.S.C. 1395x(aa)(2)],

shall be considered, for the purposes of title XVIII or XIX, respectively, of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.], as satisfying the definition of a rural health clinic under such section.”

PROMULGATION OF REGULATIONS DEFINING COSTS CHARGEABLE TO PERSONAL FUNDS OF PATIENTS IN SKILLED NURSING FACILITIES; DATE OF ISSUANCE

Pub. L. 95-142, §21(b), Oct. 25, 1977, 91 Stat. 1207, provided that: “The Secretary of Health, Education, and Welfare [now Health and Human Services] shall, by regulation, define those costs which may be charged to the personal funds of patients in skilled nursing facilities who are individuals receiving benefits under the provisions of title XVIII [42 U.S.C. 1395 et seq.], or under a State plan approved under the provisions of title XIX [42 U.S.C. 1396 et seq.], of the Social Security Act, and those costs which are to be included in the reasonable cost or reasonable charge for extended care services as determined under the provisions of title XVIII, or for skilled nursing and intermediate care facility services as determined under the provisions of title XIX, of such Act.”

[Pub. L. 95-142, §21(c)(2), Oct. 25, 1977, 91 Stat. 1208, provided that: “The Secretary of Health, Education, and Welfare shall issue the regulations required under subsection (b) [set out above] within ninety days after the date of enactment of this Act [Oct. 25, 1977].”]

HOME HEALTH SERVICES; GRANTS FOR ESTABLISHMENT, OPERATION, STAFFING, ETC., OF PUBLIC AND NON-PROFIT PRIVATE AGENCIES AND ENTITIES; PROCEDURES; PAYMENTS; AUTHORIZATION OF APPROPRIATIONS

Pub. L. 94-63, title VI, §602, July 29, 1975, 89 Stat. 346, as amended by Pub. L. 94-460, title III, §302, Oct. 8, 1976, 90 Stat. 1960; Pub. L. 95-83, title III, §310, Aug. 1, 1977, 91 Stat. 397, which provided for a program of home health services and of training of professional and paraprofessional personnel, was repealed by Pub. L. 95-626, title II, §207(b), Nov. 10, 1978, 92 Stat. 3586, effective Oct. 1, 1978.

PAYMENT FOR SERVICE OF PHYSICIANS RENDERED IN A TEACHING HOSPITAL FOR ACCOUNTING PERIODS BEGINNING AFTER JUNE 30, 1975, AND PRIOR TO OCTOBER 1, 1978; STUDIES, REPORTS, ETC.; EFFECTIVE DATES

Pub. L. 93-233, §15(a)(1), (b)-(d), Dec. 31, 1973, 87 Stat. 965, as amended by Pub. L. 93-368, §7, Aug. 7, 1974, 88

Stat. 422; Pub. L. 94-368, §1, July 16, 1976, 90 Stat. 997; Pub. L. 95-292, §7, June 13, 1978, 92 Stat. 316, provided that for the cost accounting periods beginning after June 30, 1975, and prior to October 1, 1978, subsec. (b) of this section will be administered as if paragraph (7) of subsec. (b) read as follows: "(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this title [42 U.S.C. 1395 et seq.] for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this title [42 U.S.C. 1395 et seq.]", provided for studies with respect to methods of reimbursement for physicians' services under subchapters XVIII and XIX of this chapter in hospitals which have a teaching program and a determination as to how and to what extent such funds are utilized, and provided that a final report be submitted to the Secretary of Health, Education, and Welfare, the Committee on Finance of the Senate, and the Committee on Ways and Means of the House of Representatives not later than Mar. 1, 1976.

PHYSICAL THERAPY SERVICES REQUIREMENTS;
EFFECTIVE DATE POSTPONEMENT

Pub. L. 93-233, §17(a), Dec. 31, 1973, 87 Stat. 967, provided that: "In the administration of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], the amount payable thereunder with respect to physical therapy and other services referred to in section 1861(v)(5)(A) of such Act [42 U.S.C. 1395x(v)(5)(A)] (as added by section 151(c) [251(c)] of the Social Security Amendments of 1972) shall be determined (for the period with respect to which the amendment made by such section 151(c) [251(c)] would, except for the provisions of this section, be applicable) in like manner as if the 'December 31, 1972', which appears in such subsection (d)(3) of such section 151 [251(d)(3)], set out as Effective Date of 1972 Amendment note above], read 'the month in which there are promulgated, by the Secretary of Health, Education, and Welfare, final regulations implementing the provisions of section 1861(v)(5) of the Social Security Act [42 U.S.C. 1395x(v)(5)]'."

PAYMENT FOR DURABLE MEDICAL EQUIPMENT

Pub. L. 92-603, title II, §245(a)-(c), Oct. 30, 1972, 86 Stat. 1423, provided that:

"(a) The Secretary is authorized to conduct reimbursement experiments designed to eliminate unreasonable expenses resulting from prolonged rentals of durable medical equipment described in section 1861(s)(6) of the Social Security Act [42 U.S.C. 1395x(s)(6)].

"(b) Such experiment may be conducted in one or more geographic areas, as the Secretary deems appropriate, and may, pursuant to agreements with suppliers, provide for reimbursement for such equipment on a lump-sum basis whenever it is determined (in accordance with guidelines established by the Secretary) that a lump-sum payment would be more economical than the anticipated period of rental payments. Such experiments may also provide for incentives to beneficiaries (including waiver of the 20 percent coinsurance amount applicable under section 1833 of the Social Security Act [42 U.S.C. 1395l]) to purchase used equipment whenever the purchase price is at least 25 percent less than the reasonable charge for new equipment.

"(c) The Secretary is authorized, at such time as he deems appropriate, to implement on a nationwide basis any such reimbursement procedures which he finds to be workable, desirable and economical and which are consistent with the purposes of this section."

RESPECTING THE RIGHTS OF HOSPITAL PATIENTS TO RECEIVE VISITORS AND TO DESIGNATE SURROGATE DECISION MAKERS FOR MEDICAL EMERGENCIES

Memorandum of President of the United States, Apr. 15, 2010, 75 F.R. 20511, provided:

Memorandum for the Secretary of Health and Human Services

There are few moments in our lives that call for greater compassion and companionship than when a loved one is admitted to the hospital. In these hours of need and moments of pain and anxiety, all of us would hope to have a hand to hold, a shoulder on which to lean—a loved one to be there for us, as we would be there for them.

Yet every day, all across America, patients are denied the kindnesses and caring of a loved one at their sides—whether in a sudden medical emergency or a prolonged hospital stay. Often, a widow or widower with no children is denied the support and comfort of a good friend. Members of religious orders are sometimes unable to choose someone other than an immediate family member to visit them and make medical decisions on their behalf. Also uniquely affected are gay and lesbian Americans who are often barred from the bedsides of the partners with whom they may have spent decades of their lives—unable to be there for the person they love, and unable to act as a legal surrogate if their partner is incapacitated.

For all of these Americans, the failure to have their wishes respected concerning who may visit them or make medical decisions on their behalf has real consequences. It means that doctors and nurses do not always have the best information about patients' medications and medical histories and that friends and certain family members are unable to serve as intermediaries to help communicate patients' needs. It means that a stressful and at times terrifying experience for patients is senselessly compounded by indignity and unfairness. And it means that all too often, people are made to suffer or even to pass away alone, denied the comfort of companionship in their final moments while a loved one is left worrying and pacing down the hall.

Many States have taken steps to try to put an end to these problems. North Carolina recently amended its Patients' Bill of Rights to give each patient "the right to designate visitors who shall receive the same visitation privileges as the patient's immediate family members, regardless of whether the visitors are legally related to the patient"—a right that applies in every hospital in the State. Delaware, Nebraska, and Minnesota have adopted similar laws.

My Administration can expand on these important steps to ensure that patients can receive compassionate care and equal treatment during their hospital stays. By this memorandum, I request that you take the following steps:

1. Initiate appropriate rulemaking, pursuant to your authority under 42 U.S.C. 1395x and other relevant provisions of law, to ensure that hospitals that participate in Medicare or Medicaid respect the rights of patients to designate visitors. It should be made clear that designated visitors, including individuals designated by legally valid advance directives (such as durable powers of attorney and health care proxies), should enjoy visitation privileges that are no more restrictive than those that immediate family members enjoy. You should also provide that participating hospitals may not deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability. The rulemaking should take into account the need for hospitals to restrict visitation in medically appropriate circumstances as well as the clinical decisions that medical professionals make about a patient's care or treatment.

2. Ensure that all hospitals participating in Medicare or Medicaid are in full compliance with regulations, codified at 42 CFR 482.13 and 42 CFR 489.102(a), promulgated to guarantee that all patients' advance directives, such as durable powers of attorney and health care proxies, are respected, and that patients' representatives otherwise have the right to make informed decisions regarding patients' care. Additionally, I request that you issue new guidelines, pursuant to your authority under 42 U.S.C. 1395cc and other relevant provisions of law, and provide technical assistance on how

hospitals participating in Medicare or Medicaid can best comply with the regulations and take any additional appropriate measures to fully enforce the regulations.

3. Provide additional recommendations to me, within 180 days of the date of this memorandum, on actions the Department of Health and Human Services can take to address hospital visitation, medical decision-making, or other health care issues that affect LGBT patients and their families.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§ 1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member,

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness,

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness,

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title,¹

(E) in the case of research conducted pursuant to section 1320b-12 of this title, which is not reasonable and necessary to carry out the purposes of that section,

(F) in the case of screening mammography, which is performed more frequently than is covered under section 1395m(c)(2) of this title or which is not conducted by a facility described in section 1395m(c)(1)(B) of this title, in the case of screening pap smear and screening pelvic exam, which is performed more frequently than is provided under section 1395x(nn) of this title, and, in the case of screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,

(G) in the case of prostate cancer screening tests (as defined in section 1395x(oo) of this title), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently

than is covered under section 1395m(d) of this title,

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1395w-3a(c)(6)(C) of this title for which payment is made under part B that is furnished in a competitive area under section 1395w-3b of this title, that is not furnished by an entity under a contract under such section,

(K) in the case of an initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under part B,

(L) in the case of cardiovascular screening blood tests (as defined in section 1395x(xx)(1) of this title), which are performed more frequently than is covered under section 1395x(xx)(2) of this title,

(M) in the case of a diabetes screening test (as defined in section 1395x(yy)(1) of this title), which is performed more frequently than is covered under section 1395x(yy)(3) of this title,

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1395x(s)(2)(AA) of this title,

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1395x(ggg) of this title), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this chapter and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1395x(aa)(1) of this title, in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, in the case of services for which payment may be made under section 1395qq(e) of this title, and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1395f(f) of this title and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this subchapter, physicians' services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

¹ See References in Text note below.