§ 1395w–154. Improved Medicare prescription drug plan and MA–PD plan complaint system

(a) In general

The Secretary shall develop and maintain a complaint system, that is widely known and easy to use, to collect and maintain information on MA–PD plan and prescription drug plan complaints that are received (including by telephone, letter, e-mail, or any other means) by the Secretary (including by a regional office of the Department of Health and Human Services, the Medicare Beneficiary Ombudsman, a subcontractor, 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).

Editorial Notes

AMENDMENTS


§ 1395x. Definitions

In this section:

(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

(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

(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).

Editorial Notes

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

Editorial Notes

CODIFICATION


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

(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, (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 pro-
viding, 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 1395d, 1395f(f), and 1395n of this title and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1395b(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 (mm)(1)) or a rural emergency hospital (as defined in subsection (mm)(1)) or a critical access hospital (as defined in section 1395bb of this title and which meets the other requirements of this subsection to be met in the case of accredited institutions, see section 139555 of this title). 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 13951–5 of this title. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 139555 of this title. The term “hospital” also includes a facility 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 require-\(^1\) So in original.
ments 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 code 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)) or a rural emergency hospital (as defined in subsection (kkk)(2)).

(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”.

1 So in original.
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(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; and

(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 sub-
chapter that the procedures established pursuant to subchapter XIX be utilized instead of the procedures required by this section.

(i) Agreements for transfer between skilled nurs-
ing 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 be-
tween them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which con-
trols them, there is reasonable assurance that—
(1) transfer of patients will be effected be-
tween the hospital and the skilled nursing fac-
cility whenever such transfer is medically ap-
propriate as determined by the attending phy-
sician; and
(2) there will be interchange of medical and
other information necessary or useful in the
care and treatment of individuals transferred
to the institution, or in determining
whether such individuals can be adequately
cared for otherwise than in either of such in-
stitutions.

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 fa-
cility is situated) with which 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 pa-
tients and the information referred to in para-
graph (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, a
nurse practitioner or a clinical nurse specialist
(as those terms are defined in subsection
(aa)(5)), or a physician assistant (as defined in
subsection (aa)(5)), 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) estab-
lished and periodically reviewed by a physi-
cian, a nurse practitioner, a clinical nurse spe-
cialist or a physician assistant, which items
and services are, except as provided in para-
graph (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 reg-
istered professional nurse;
(2) physical or occupational therapy or
speech-language pathology services;
(3) medical social services under the direc-
tion of a physician, a nurse practitioner, a
clinical nurse specialist, or a physician assistant;
(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
osteoarthritis 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(a)(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 hos-
pital, under a teaching program of such hos-
pital 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 facil-
ity, or at a rehabilitation center which meets
such standards as may be prescribed in regula-
tions, 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 indi-
vidual 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
(ii)(1)). 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
1395m(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 cir-
cumstances when the need for additional care is
finite and predictable).

(n) Durable medical equipment

The term “durable medical equipment” in-
cludes iron lungs, oxygen tents, hospital beds,
and wheelchairs (which may include a power-op-
erated 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, nurse practitioners or clinical nurse specialists (as those terms are defined in subsection (aa)(5)), certified nurse-midwives (as defined in subsection (gg)), or physician assistants (as defined in subsection (aa)(5)) 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, nurse practitioner, clinical nurse specialist, certified nurse-midwife, physician assistant, 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 (2);

(6) meets the conditions of participation specified in section 1395bb(b)(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 pursu-
[The text of the page is not legible due to low contrast and resolution. Please refer to the original print version for readability.]
(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 (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 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;

(ii) 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)); and

(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 whose condition is not self-managed;

(ii) 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)); and

(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 whose condition is not self-managed;

(ii) 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;
(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 (hhh)) 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 provisional 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 COVID–19 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 (hh));
(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 333 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 Pharmacopeia, 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 and 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 has 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, rural emergency 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 estimates 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

*So in original. Probably should be “have”.
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) 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 sufficient 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 (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 are 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 on 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 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 regulations 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 reasonable costs in the same area for similar services provided in physicians' 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 pro-
vided 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, 1995, and before July 1, 1996, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies,

(II) July 1, 1996, and before July 1, 1997, 115 percent of such mean,

(III) July 1, 1997, 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, 105 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1996, 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 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 nonroutine 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.

(viii)(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)(II) 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 ½ 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").

(ii) 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) is 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 occurring during 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 XXVI 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, except 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 1395l(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 1395l(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 1395l(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)(v) and 1395(n)(1)(B)(v) of this title, respectively, shall be reduced in accordance with such subclause. ²

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

(I) for cost reporting periods beginning during fiscal year 1998, by 40 percent of such amount otherwise allowable,

(ii) for cost reporting periods beginning during fiscal year 1999, by 25 percent of such amount otherwise allowable,

(iii) for cost reporting periods beginning during fiscal year 2000, by 20 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.

(W) 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), (A)

(2) A 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 psy-
chiatric 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 subclause (q) of such section) 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.

(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 ac-

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\(^8\) See References in Text note below.
cess 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 110 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 1395–5 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) applies 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 deductible 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 $500,000 (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 and approved 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.

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 1395x 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 improvement 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) 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)(4) 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 322(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 322(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 322(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 1395 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 satisfying 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 (dd)(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;
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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) 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 outpatients 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 the services described in subpara-
graphs (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 in 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.

(5)(A) The Secretary may waive the requirements of paragraph (2)(A)(ii)(D) 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); and

(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)(ii) 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 nonroutine 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)(i)(I). The provisions of paragraph (2)(A)(i)(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 extended care services. 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), 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),

So in original. Probably should be “paragraph (2)(D)(i)".
(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)(I) provides the mental health services described in section 1913(o)(1) of the Public Health Service Act [42 U.S.C. 300x-2(o)(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);

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

(iii) 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 furnishing 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 physician's 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 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, nurse practitioner or clinical nurse specialist (as those terms are defined in subsection
(aa)(5), certified nurse-midwife (as defined in subsection (gg)), or physician assistant (as defined in subsection (aa)(5)) 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)).

(ii) 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 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 1395i–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.

(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 appro-
(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 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; and
(ii) is not affiliated with—

(I) a provider of medical treatment or services; or
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(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 institution 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 nonmedical 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.
(v) 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, 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:

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

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

(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)(l).

(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 di-
abetes (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 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 nonmedical 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 1395x–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

(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) 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 or early detection of an illness or disability for long-term care hospitals, 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; and
   (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

(ii) after December 31, 2006.
(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 1395fff(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 described in paragraph (3) and has shown, in peer-reviewed published research, that it accomplished—

(i) one or more of the following:

(1) positively affected the progression of coronary heart disease;

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

(3) 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:

(1) low density lipoprotein;

(2) triglycerides;

(3) body mass index;

(4) systolic blood pressure;

(5) diastolic blood pressure; or

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

(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) had a heart or heart-lung transplant;

(viii) had stable angina pectoris;

(ix) had heart valve repair or replacement;

(x) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; and

(xi) had a heart or heart-lung transplant.

(C) An intensive cardiac rehabilitation program may be provided in a series of 72 one-hour sessions (as defined in section 1395w–4(b)(3) 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 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 individual\(^1\) in the program.

(ff) 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 individual\(^1\) in the program.

(gg) 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 appro-
priate), 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 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 1395x 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.

Clause (ii) shall not apply to a self-administered drug or biological on a self-administered drug exclusion list if such drug or biological was included as a transitional home infusion drug under subparagraph (A)(iii) of section 1395m(u)(7) of this title and was identified by a HCPCS code described in subparagraph (C)(ii) of such section.

(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 of 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.

(kkk) Rural emergency hospital services; rural emergency hospital

(1) Rural emergency hospital services

(A) In general

The term “rural emergency hospital services” means the following services furnished by a rural emergency hospital (as defined in paragraph (2)) that do not exceed an annual per patient average of 24 hours in such rural emergency hospital:
(i) Emergency department services and observation care.

(ii) At the election of the rural emergency hospital, with respect to services furnished on an outpatient basis, other medical and health services as specified by the Secretary through rulemaking.

(B) Staffed emergency department

For purposes of subparagraph (A)(i), an emergency department of a rural emergency hospital shall be considered a staffed emergency department if it meets the following requirements:

(1) The emergency department is staffed 24 hours a day, 7 days a week.

(ii) A physician (as defined in subsection (r)(1)), nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in subsection (aa)(5)) is available to furnish rural emergency hospital services in the facility 24 hours a day.


(2) Rural emergency hospital

The term “rural emergency hospital” means a facility described in paragraph (3) that—

(A) is enrolled under section 1395ww(d)(1)(B) of this title, submits the additional information at such time and in such form as the Secretary may require:

(i) the requirements of a staffed emergency department as described in paragraph (1)(B);

(ii) applicable staffing and staffing responsibilities as the Secretary may require;

(iii) applicable by the Secretary;

(iv) conditions of participation applicable to—

(I) critical access hospitals, with respect to emergency services under section 485.618 of title 42, Code of Federal Regulations (or any successor regulation); and

(II) hospital emergency departments under this subchapter, as determined applicable by the Secretary;

(v) such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished rural emergency hospital services; and

(vi) in the case where the rural emergency hospital includes a distinct part unit of the facility that is licensed as a skilled nursing facility, such distinct part meets the requirements applicable to skilled nursing facilities under this subchapter.

(3) Facility described

A facility described in this paragraph is a facility that as of December 27, 2020—

(A) was a critical access hospital; or

(B) was a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1395ww(d)(2)(D) of this title), or was a subsection (d) hospital (as so defined) with not more than 50 beds that was treated as being located in a rural area pursuant to section 1395ww(d)(8)(E) of this title.

(4) Additional information

(A) Information

For purposes of paragraph (2)(A), a facility that submits an application for enrollment under section 1395cc(j) of this title as a rural emergency hospital shall submit the following information at such time and in such form as the Secretary may require:

(i) An action plan for initiating rural emergency hospital services (as defined in paragraph (1)), including a detailed transition plan that lists the specific services that the facility will—

(I) retain;

(II) modify;

(iii) add; and

(IV) discontinue.

(ii) A description of services that the facility intends to furnish on an outpatient basis pursuant to paragraph (1)(B).

(iii) Information regarding how the facility intends to use the additional facility payment provided under section 1395m(x)(2) of this title, including a description of the services covered under this subchapter that the additional facility payment would be supporting, such as furnishing telehealth services and ambulance services, including operating the facility and maintaining the emergency department to provide such services covered under this subchapter.

(iv) Such other information as the Secretary determines appropriate.

(B) Effect of enrollment

Such enrollment shall remain effective with respect to a facility until such time as—

(i) the facility elects to convert back to its prior designation as a critical access hospital or a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title), subject to requirements applicable under this subchapter for such designation and in accordance with procedures established by the Secretary; or

(ii) the Secretary determines the facility does not meet the requirements applicable to a rural emergency hospital under this subchapter.

11 So in original. Probably should be followed by a semicolon.
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(5) Licensure

A facility may not operate as a rural emergency hospital in a State unless the facility—
(A) is located in a State that provides for the licensing of such hospitals under State or applicable local law; and
(B)(i) is licensed pursuant to such law; or
(ii) is approved by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing.

(6) Discretionary authority

A rural emergency hospital may—
(A) include a unit of the facility that is a distinct part licensed as a skilled nursing facility to furnish post-hospital extended care services; and
(B) be considered a hospital with less than 50 beds for purposes of the exception to the payment limit for rural health clinics under section 1395(f) of this title.

(7) Quality measurement

(A) In general

The Secretary shall establish quality measurement reporting requirements for rural emergency hospitals, which may include the use of a small number of claim-based outcomes measures or surveys of patients with respect to their experience in the rural emergency hospital, in accordance with the succeeding provisions of this paragraph.

(B) Quality reporting by rural emergency hospitals

(i) In general

With respect to each year beginning with 2023, (or each year beginning on or after the date that is one year after one or more measures are first specified under subparagraph (C)), a rural emergency hospital shall submit data to the Secretary in accordance with clause (ii).

(ii) Submission of quality data

With respect to each such year, a rural emergency hospital shall submit to the Secretary data on quality measures specified under subparagraph (C). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(C) Quality measures

(i) In general

Subject to clause (ii), any measure specified by the Secretary under this subparagraph must have been endorsed by the entity with a contract under section 1395aaa(a) of this title.

(ii) Exception

In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1395aaa(a) of this title, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(iii) Consideration of low case volume when specifying performance measures

The Secretary shall, in the selection of measures specified under this subparagraph, take into consideration ways to account for rural emergency hospitals that lack sufficient case volume to ensure that the performance rates for such measures are reliable.

(D) Public availability of data submitted

The Secretary shall establish procedures for making data submitted under subparagraph (B) available to the public regarding the performance of individual rural emergency hospitals. Such procedures shall ensure that a rural emergency hospital has the opportunity to review, and submit corrections for, the data that is to be made public with respect to the rural emergency hospital prior to such data being made public. Such information shall be posted on the Internet website of the Centers for Medicare & Medicaid Services in an easily understandable format as determined appropriate by the Secretary.

(8) Clarification regarding application of provisions relating to off-campus outpatient department of a provider

Nothing in this subsection, section 1395(a)(10) of this title, or section 1395m(x) of this title shall affect the application of paragraph (1)(B)(v) of section 1395(f) of this title, relating to applicable items and services (as defined in subparagraph (A) of paragraph (21) of such section) that are furnished by an off-campus outpatient department of a provider (as defined in subparagraph (B) of such paragraph).

(9) Implementation

There shall be no administrative or judicial review under section 1385ff of this title, 1395eo of this title, or otherwise of the following:

(A) The determination of whether a rural emergency hospital meets the requirements of this subsection.

(B) The establishment of requirements under this subsection by the Secretary, including requirements described in paragraphs (2)(D), (4), and (7).

(C) The determination of payment amounts under section 1395m(x) of this title, including the additional facility payment described in paragraph (2) of such section.


(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, 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.

Editorial Notes

REFERENCES IN TEXT

Section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (kkk)(2), 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. (kkk)(2), 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)(4)(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 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. 3025.


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. 94–417, Sept. 30, 1976, 90 Stat. 1461. Title V of the Act is classified generally to subchapter IV (§14651 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.


AMENDMENTS

2020—Subsec. (e). Pub. L. 116–260, §125(a)(1)(A), inserted before period at end of concluding provisions “or a rural emergency hospital (as defined in subsection (kkk)(2))”.

Subsec. (m). Pub. L. 116–136, §3708(c)(1)(A), in introductory provisions, inserted “—a nurse practitioner, a clinical nurse specialist (as those terms are defined in subsection (aa)(5)), or a physician assistant (as defined in subsection (aa)(5))” before “care of a physician” and “—a nurse practitioner, a clinical nurse specialist, or a physician assistant” after “reviewed by a physician”.

Subsec. (m)(3). Pub. L. 116–136, §3708(c)(1)(B), inserted “or a nurse practitioner, a clinical nurse specialist, or a physician assistant” after “‘physician’”.

Subsec. (o)(2). Pub. L. 116–136, §3708(c)(2), inserted “nurse practitioners or clinical nurse specialists (as those terms are defined in subsection (aa)(5)), certified nurse-midwives (as defined in subsection (gg)), or physician assistants (as defined in subsection (aa)(5))” after “‘physicians’” and “—nurse practitioner, clinical nurse specialist, certified nurse-midwife, physician assistant,” after “‘physician’”.


Subsec. (dd)(4)(C). Pub. L. 116–260, §407(a)(4)(A), struck out subpar. (C) which read as follows: “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 agen-
cy, 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.

Subsec. (kkk)(1). Pub. L. 115–123, § 5708(c)(3), inserted ‘‘, nurse practitioner or clinical nurse specialist (as those terms are defined in subsection (aa)(5))’’, certified nurse-midwife (as defined in subsection (gg)), or physical assistant (as defined in subsection (aa)(5))’’ after ‘‘attending physician’’. Subsec. (lll)(3)(C). Pub. L. 115–271, § 117(a), inserted concluding provisions.


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paragraph (3)” for “not otherwise described in this subchapter”.
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 subchapter 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.

2006—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)(1) of this title, or is accredited by a national accreditation body recognized by the Secretary under section 1395bb(a)(1), 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 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, § 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. (aa)(3). Pub. L. 109–171, § 5112(a)(1), substituted “and services described in subsections (pp) and (vv); and” for “, and” in subpar. (A) and “section 330” for “sections 329, 330, and 360” 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. (s)(2)(A). Pub. L. 108–173, § 303(1)(2), inserted “or would have been so included but for the application of section 1395w–3b of this title” after “included in the physicians’ bills”.

Pub. L. 108–173, § 901(b), added subsec. (s)(2)(A), inserted “services described in subsection (ww)(1)” after “services which would be physicians’ services”.
Subsec. (s)(2)(K)(i). Pub. L. 108–173, § 611(d)(2), inserted “and services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Section 1395w–3b(a)(1) of this title’’; and inserted into the physicians’ bills’’.


Subsec. (s)(2)(Z). Pub. L. 108–173, § 738(b)(11), substituted “services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Subsec. (s)(2)(W). 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)(Z). Pub. L. 108–173, § 738(b)(11), substituted “services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Subsec. (s)(2)(W). 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)(Z). Pub. L. 108–173, § 738(b)(11), substituted “services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Subsec. (s)(2)(W). 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)(Z). Pub. L. 108–173, § 738(b)(11), substituted “services described in subsection (ww)(1)” after “services which would be physicians’ services”.

Subsec. (s)(7). Pub. L. 108–173, § 415(b), inserted “subject to section 1395m(l)(14) of this title,” after “large,” inserted closing parenthesis after “as defined in section 1395w(d)(5)(D)(ii) of this title”.


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)”.


serve the area in which the patient resides”.


Subsec. (aa)(a). 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)(vi). Pub. L. 105–33, § 4201(c)(1), substituted “critical access” for “rural primary care” in prov. (1) and (2).

Subsec. (b)(4). Pub. L. 105–33, § 451(a)(2)(B), substituted “subject to subsection (s)(2)(K)” for “clauses (i) or (iii) of subsection (s)(2)(K)”.

Subsec. (e). Pub. L. 105–33, § 454(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 sanitarium, operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts”.

Subsec. (mm)(1). Pub. L. 105–33, § 4201(c)(1), substituted “critical access” for “rural primary care” in prov. (1) and (2).

Subsec. (h). Pub. L. 105–33, § 449(a)(10), substituted “paragraphs (3), (6), and (7)” for “paragraphs (3) and (6)” in introductory provisions.

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Subsec. (pp)(2). Pub. L. 106–554, § 110(a)(6) [title I, § 103(a)(2)], substituted “An” for “in paragraph (1)(C), an”.


1999—Subsec. (o)(7). Pub. L. 106–113, § 1000(a)(6) [title III, § 309(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;”.

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)(vi). Pub. L. 105–33, § 4201(c)(1), substituted “critical access” for “rural primary care” in prov. (1) and (2).


Subsec. (eee)(3). Pub. L. 106–113, § 1000(a)(6) [title V, § 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.


1998—Subsec. (vv)(vI)(I) to (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 “and” at end, and added subcl. (V).


1997—Subsec. (a). Pub. L. 105–33, § 4201(c)(1), substituted “critical access” for “rural primary care” in prov. (1) and (2).

Subsec. (b)(4). Pub. L. 105–33, § 451(a)(2)(B), substituted “subject ‘subsection (s)(2)(K)” for “clauses (i) or (iii) of subsection (s)(2)(K)”.

Subsec. (e). Pub. L. 105–33, § 454(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 sanitarium, operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts” and inserted “consistent with section 1391–5 of this title” before the period.

Pub. L. 105–33, § 4201(c)(1), substituted “critical access” for “rural primary care” in prov. (1) and (2).

Subsec. (h). Pub. L. 105–33, § 449(a)(10), substituted “paragraphs (3), (6), and (7)” for “paragraphs (3) and (6)” in introductory provisions.
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Subsec. (h)(7). Pub. L. 105–33, § 4322(b)(5)(D)(ii), inserted before seminalicol in first sentence “,” and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type 1 or Type 2 diabetes (as determined under standards established by the Secretary in consultation with the appropriate organizations)."

Subsec. (o). Pub. L. 105–33, § 4312(b)(1)(A), 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. (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, § 4512(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)(1)(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 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). Pub. L. 105–33, § 4102(c), 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. (s)(2)(R). Pub. L. 105–33, § 4104(a)(1)(A), added subcl. (iv) of clause (ii) of section 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. (s)(12)(A). Pub. L. 105–33, § 4102(a)(1)(A), 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)(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)” for “the financial security requirement described in subsection (o)(7)”.

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)(ii). 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)(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 any asset not in existence as of August 5, 1997, the first owner of record of the asset as of August 5, 1997,’’ for ‘‘the lesser of the allow-
able 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, 1994.


Subsec. (v)(7)(D). Pub. L. 105–33, § 4432(b)(5)(E), inserted “subsections (a) through (c) of” before “section 1395yy of this title”.


Subsec. (w). Pub. L. 105–33, § 4201(c)(1), substituted “critical access” for “rural primary care” wherever appearing.


Subsec. (y)(1). Pub. L. 105–33, § 4454(a)(1)(B)(ii), which directed the amendment of this subsec. by inserting “consistent with section 1395–5 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, § 4453(a)(1)(B)(ii), substituted “a religious nonmedical health care institution (as defined in subsection (ss)(1)))” for “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)(3), (2), in cl. (1) 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 that is designated by the Secretary”.

Subsec. (aa)(2)(I). Pub. L. 105–33, § 4205(b)(1), amended subpar. (I) generally. Prior to amendment, text 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). 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 this subchapter”.


Subsec. (dd)(2)(A)(ii)(I). Pub. L. 105–33, § 4445(1), substituted “subparagraphs (A), (C), (F), 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 clause (i), under contract with” after “employed by”.


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. (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 1395–4(i)(2) of this title.

‘‘(2) The term ‘inpatient rural primary care hospital’ 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’ means medical and other health services furnished by a rural primary care hospital’.

Subsec. (nn). Pub. L. 105–33, § 4103(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 period of time 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. (aa)(4)(A)(1)(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.


Subsec. (aa)(2). Pub. L. 103–432, § 102(g)(4)(B), substituted “hospital or rural primary care hospital” for “hospital”.


Subsec. (aa)(4). 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, § 4154(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 purposes of paragraphs (1) and (2)”. Substituted former par. (4) as (5) and added subpar. (B).


Subsec. (ak). Pub. L. 101–239, § 6003(c)(3)(D)(X), 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)).”

Subsec. (a). Pub. L. 101–234, § 201(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. (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).


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. (s). Pub. L. 101–239, § 6112(a)(1), amended par. (5) generally. Prior to amendment, par. (5) read as follows: “medical supplies (other than drugs and biologics) and durable medical equipment, while under such a plan”.

Subsec. (aa). 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. (gg)(L). 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. (gg)(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. (i).

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Subsec. (a)(13). Pub. L. 101–239, § 201(a), which repealed Pub. L. 100–360, § 201(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 (14) as (15) by Pub. L. 101–239, § 201(a)(1)(C), see 1988 Amendment note below.


Pub. L. 101–239, § 201(a), which repealed Pub. L. 100–360, § 201(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, § 201(a)(1)(C), see 1988 Amendment note below.


Pub. L. 101–239, § 201(a), which repealed Pub. L. 100–360, § 201(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, § 201(a)(1)(C), see 1988 Amendment note below.


Subsec. (t). Pub. L. 101–239, § 201(a), repealed Pub. L. 100–360, § 201(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.


Pub. L. 101–239, § 201(a), repealed Pub. L. 100–360, § 201(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. (v)(1)(G)(I). Pub. L. 101–239, § 201(a), repealed Pub. L. 100–360, § 201(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. (v)(2)(A). Pub. L. 101–239, § 201(a), inserted `"and paragraph (7) of this subsection,"' for "paragraph (7) of this subsection, and subsection (1) 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, 1395f(f)(2) of this title, and subsection (i) of this section," substituted `"and section 1395f(2) of this title"' for "section 1395f(2) of this title, and subsection (i) of this section;" and struck out `"except for purposes of subsection (a)(2),"' after "such term shall not" in fifth sentence.

Subsec. (i). Pub. L. 101–239, § 201(a)(1)(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 1395f(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;".


Pub. L. 100–360, § 411i(d)(1)(D), inserted: "except that such term does not include such equipment furnished by a supplier who has used, for the demonstra-
tion 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. 100–617, §4242(a), inserted at end “Nothing in this subsection shall be construed as requiring, with respect to outpatient services which 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)(2)(J). Pub. L. 100–360, §203(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)(1). Pub. L. 100–360, §204(d)(23)(B), substituted “nursing facility (as defined in section 1396a(a) of this title)” for “intermediate care facility (as defined in section 1396d(c) of this title)”.


Subsec. (s)(13). Pub. L. 100–360, §204(a)(1)(1)(B)–(D), added par. (13) relating to screening mammography (as defined in subsection (kk) of this section). Former par. (13) redesignated (14).


Pub. L. 100–360, §204(a)(1)(A), redesignated par. (14) as (15).


Subsec. (t). Pub. L. 100–360, §203(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. (v)(1)(L)(iii). Pub. L. 100–360, §411(d)(5)(A), substituted “verified” for “audited” in subs. (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. (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)(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)(IV), (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)(V), struck out par. (4) which provided that certain determinations about services provided by an institution described in par. (1) be made under regulations.


Subsec. (f)(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. (i). Pub. L. 100–617, §8422(a), inserted “on-site” before “at a community health center” 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 “Public Health Service Act”.


Pub. L. 100–360, §203(b), added subsec. (j) relating to in-home intravenous drug therapy services.


1987—Subsec. (a)(2). Pub. L. 100–203, §4201(d)(1), formerly §4201(d), as redesignated and amended by Pub. L. 100–360, §411(h)(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(a)(9), substituted “anesthesia for “, anesthesia” and “certified registered nurse” for “certified registered nurse”.


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(a)(10), made technical amendment to heading.
Subsec. (r). Pub. L. 100–203, § 4066(b), substituted "and partial hospitalization services incident to such services" for "but not included under subsection (b) of this section if it were furnished to an inpatient of a hospital; or".


Subsec. (s)(2). Pub. L. 100–203, § 4065(a), added subpar. (S).

Subsec. (s)(3). Pub. L. 100–203, § 4065(a), added subpar. (S).


Subsec. (mm). Pub. L. 100–203, § 4077, added subpar. (S).


Subsec. (v)(1)(B). Pub. L. 99–272, §1907(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)(O)(1). Pub. L. 99–272, §9110(a)(1), inserted “except as provided in clause (iv)” after “such regulations shall provide.”


Subsec. (cc)(1)(F). Pub. L. 98–369, §2354(b)(29), substituted “or” for “or” “home health agency”.


Subsec. (v)(1)(E). Pub. L. 98–369, §2354(b)(21)(D), 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)(G). Pub. L. 98–369, §2354(b)(24), substituted “the Secretary, or upon request by the Comptroller General” for “to the Secretary, or upon request to the Comptroller General”.


Subsec. (v)(1)(P). Pub. L. 98–369, §2319(a)(2), 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 1395(a), 1395k(a)(2)(F)(ii), and 1395n of this title” for “under subsections (k) and (m) and sections 1395(a) and 1395n of this title” before “is consistent with the policy”.

Subsec. (v)(2). Pub. L. 98–369, §2342(a), substituted “by a physician as so defined” for “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. (v)(3). 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”.

Subsec. (v)(4). Pub. L. 98–369, §2312(a), inserted “(except as provided in clause (ii))” before “the Secretary may determine.”, and substituted in lieu of “for use 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.”  “(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, with appropriate adjustment for administrative and general costs of hospital-based agencies.”

Subsec. (v)(5). Pub. L. 98–369, §2319(a)(1), struck out “the Secretary, or upon request by the Comptroller General”.


See subsec. (n) of this section.

Subsec. (v)(7). Pub. L. 98–369, §2323(a), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (u). Pub. L. 98–369, §2345(b)(20), struck out “or” before “home health agency”.

Subsec. (v)(8). Pub. L. 98–369, §2332(a), substituted “sections 1395(a), 1395k(a)(2)(F)(ii), and 1395n of this title but only if” for “sections 1395(a) and 1395n of this title but only if”.


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, §2333(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, §2333(b)(1), struck out subsec. (g) which defined “tuberculosis hospital”.

Subsec. (h). Pub. L. 98–369, §2335(b)(5), in provisions following par. (15), struck out “or tuberculosis” after “treatment of mental diseases”.

Subsec. (i)(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. (dd)(2)(A)(i)(I). Pub. L. 98–369, § 2343(a), inserted "except as otherwise provided in paragraph (5),".


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 subj. (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. (z)(2). Pub. L. 98–21, § 607(d), designated existing provisions as subpars. (A) and added subpar. (B).

Pub. L. 98–21, § 607(b)(2), substituted "$600,000" for "$100,000" or such lesser amount as may be established by the State under section 1320a–1(q)(1) of this title in which the hospital is located)" for "$100,000" or such lesser amount as may be established by the State under section 1320a–1(q)(1) of this title in which the hospital is located)".

1982—Subsec. (e)(C). Pub. L. 97–248, § 248–4, § 248–14, substituted "108 percent of the mean of such 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 comparable or lower limit as the Secretary could determine, and struck out "(i)".

Pub. L. 97–248, § 105(a), inserted "free standing" after "costs per visit for".


Subsec. (v)(7). Pub. L. 97–248, § 101(d), redesignated existing provisions as subpars. (A) and added subpar. (B).


Subsec. (w)(1). Pub. L. 97–248, § 122(d)(2), substituted "home health agency, or hospice program for " or "home health agency".


or less located in an area determined by the Secretary to meet definition relating to a rural area described in subparagraph (A) of paragraph (5) and excepting provisions to such definition. 

Subsec. (i). Pub. L. 94–485, §950(a), struck out former cl. (C). 

Subsec. (j)(1). Pub. L. 94–485, §950(b), substituted provisions relating to compliance with requirements of section 1395x–3 of this title, for provisions relating disclosure of ownership, control, status, etc., information to the Secretary or his delegate. 

Subsec. (j)(13). Pub. L. 94–485, §21a(a), struck out “and” after “nursing facilities”.


Subsec. (m). Pub. L. 95–216, §217(d), reorganized existing second sentence of subsec. (b) as par. (6) and in subsec. (b)(d) as so redesignated inserted 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. (s). Pub. L. 95–216, §217(c), added par. (7).

Subsec. (v). Pub. L. 93–646, §211(b), inserted reference to section 1395f(f)(2) of this title in the provisions preceding par. (1), inserted reference to sections 1395f(e)(2) of this title “For purposes of sections 1395f(d) and 1395a(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. (x). Pub. L. 93–646, §211(d), reorganized existing second sentence of subsec. (b) as par. (6) and in subsec. (b)(d) as so redesignated inserted 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. (z). Pub. L. 93–646, §217(d), inserted provisions for accreditation by the Joint Commission on Accreditation of Hospitals.

Subsec. (aa). Pub. L. 95–216, §217(d), inserted provisions for accreditation by the Joint Commission on Accreditation of Hospitals.

Subsec. (j)(15). Pub. L. 92–603, §§234(d), 246(b)(2), (4), 267, 278(b)(11), redesignated former par. (19) 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), 238(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 inpatient 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 1396x(a)(2)(E) of this title,”, inserted provision so as to include doctors in optical arts who are legally authorized to practice such art in the country in which inpatient hospital services referred to in section 1395f(d) of this title are furnished, and inserted 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 1395(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), 267, 278(b)(11), inserted definition of the costs of services, inserted provision that the regulations for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services of groups of items or services to be recognized as reasonably 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)(6). Pub. L. 92–603, §§222(a), 231(c), redesignated former par. (4) as (6).


Subsec. (w). Pub. L. 92–603, §278(a)(14), (15), substituted “skilled nursing facility” for “extended care facility” and “a” for “an”.

Subsec. (x). 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. (y). 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. (a). 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 “the inclusion of chiropractor services”, and inserted “other than in institutional settings” after “the inclusion of chiropractor services”. Subsec. (b). Pub. L. 90–248, §185(a), added cl. (4) providing for the Federal inpatient hospital prospective payment system.

Subsec. (c). Pub. L. 90–248, §185(c), added cl. (5) providing for the Federal diagnosis-related group payment system.

Subsec. (d). Pub. L. 90–248, §185(d), struck out “‘(unless they would otherwise constitute inpatient hospital services, extended care services, or home health services)” after “the inclusion of chiropractor services”, and inserted “other than in institutional settings” after “the inclusion of chiropractor services”.

Subsec. (e). Pub. L. 90–248, §185(e), added cl. (6) providing for the Federal insurance claims system.
amendment by section 125(a)(1), (d)(1) of Pub. L. 116–136 applicable to items and services furnished on or after Jan. 1, 2023, see section 125(g) of Pub. L. 116–260, set out as a note under section 1395w–21 of this title.

**Effective Date of 2020 Amendment**

Pub. L. 116–260, div. CC, title I, § 117(b), Dec. 27, 2020, 134 Stat. 2950, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 2021."

Amendment by section 125(a)(1), (d)(1) of Pub. L. 116–260 applicable to items and services furnished on or after Jan. 1, 2023, see section 125(g) of Pub. L. 116–260, set out as a note under section 1395w–19 of this title.

Secretary of Health and Human Services to prescribe regulations to apply the amendments made by section 3708 of Pub. L. 116–136 to items and services furnished, which shall become effective no later than 6 months after Mar. 27, 2020, see section 3708(f) of Pub. L. 116–136, set out as a note under section 1395w–19 of this title.

Amendment by section 373(a)(3) of Pub. L. 116–136 effective on Mar. 27, 2020, and applicable with respect to a COVID–19 vaccine beginning on the date that such vaccine is licensed under section 262 of this title, see section 373(d)(2) of Pub. L. 116–136, set out as a note under section 1395w–19 of this title.

**Effective Date of 2018 Amendment**


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 1396f 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 504(d) of Pub. L. 114–255, set out as a note under section 1395f 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 502(d) of Pub. L. 114–113, set out as a note under section 1395f 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 1392c of this title.

**Effective Date of 2010 Amendment**

Pub. L. 111–112, 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 410(a), (b) of Pub. L. 111–148 applicable to services furnished on or after Jan. 1, 2011, see section 410(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.

Amendment by section 410(a) of Pub. L. 111–148 applicable to items and services furnished on or after Jan. 1, 2011, see section 410(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.


**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 1395f 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 6 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 1395wb 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 1396f–2 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 1395f–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 1395wb–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 1395f 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 1395f 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 furnished on or after Jan. 1, 2005, see section 512(d) of Pub. L. 108–173, set out as a note under section 1395f of this title.

Amendment by section 611(a), (b), (d)(2) of Pub. L. 106–113 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. 106–173, 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. 2396, 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. 2396, 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 1385f of this title.

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–488, 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–488, 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, §105(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 1395f 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 amendment 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 1395f 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 1395f of this title.


Amendment by section 1000(a)(6) [title III, §321(k)(7)] of Pub. L. 108–173, 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."


**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(a) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4103(a) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4103(c) of Pub. L. 105–33, set out as a note under section 1395f 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(c) of Pub. L. 105–33, set out as a note under section 1395f 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(e)(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(d)(4), Aug. 5, 1997, 111 Stat. 378, 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. 1395f et seq.) on the date of enactment of this Act, on the date of the enactment of this Act [sic].

(2) GRANDFATHERED CLINICS.—

"(i) In general.—The amendment made by paragraph (3)(A) [amending this section] 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]."

Amendment by section 4322(b)(5)(D), (E) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1996, see section 4322(d) of Pub. L. 105–33, set out as a note under section 1395l–3 of this title.

Pub. L. 105–33, title IV, §4444(b), Aug. 5, 1997, 111 Stat. 422, 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 4444(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 the 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 1395f of this title.


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 subsection (a) [amending this section] shall 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


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 be applied 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 263(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.


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. 101–506, see section 147(g) of Pub. L. 103–432, set out as a note under section 1332a–3a of this title.


EFFECTIVE DATE OF 1993 AMENDMENT


Pub. L. 103–66, title XIII, §13555(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, §13558(b), 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, §13556(c), Aug. 10, 1993, 107 Stat. 607, provided that: "The amendments made by this section [amending this section and section 1395r
of this title shall apply to erythropoietin furnished on or after January 1, 1994.

**Effective Date of 1990 Amendment**


Amendment by section 4132(a)(2) of Pub. L. 101–508 applicable to items and services furnished on or after Jan. 1, 1990, see section 4132(a)(3) of Pub. L. 101–508, set out as a note under section 1395m of this title.

Amendment by section 4152(a)(2) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1990, see section 4152(a)(3) of Pub. L. 101–508, set out as a note under section 1395d of this title.

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(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.

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 1395k of this title.

Amendment by section 4201(d)(3), Nov. 5, 1990, 104 Stat. 3803, provided that "The amendment made by paragraph (1) [amending this section] shall be effective Jan. 1, 1990, except as otherwise provided, and applicable with respect to home health agency cost reporting periods beginning on or after January 1, 1989."

Amendment by section 4201(d)(4) of Pub. L. 101–360 applicable 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 and services furnished on or after Jan. 1, 1990, see section 202(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 1395m of this title.

Amendment by section 206(b) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 206(f) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 4202(b) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 4202(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 4203(b) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 4203(g) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 4204(a) of Pub. L. 100–360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 4204(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Mr. 390(b), Mr. 390(a), Mr. 390(a) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 4205(b) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 4205(f) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 4206(b) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 4206(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.
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, § 409(a)(2), July 1, 1988, 102 Stat. 773, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to drug furnished on or after the date of the enactment of this Act [Dec. 22, 1987]."

Pub. L. 100–203, title IV, § 4072(e)(2), Dec. 22, 1987, 101 Stat. 1339–120, provided that: "(1) The provisions of subsection (e) of section 4072 of this title shall apply to this section 
[amending this section] shall become effective on January 1, 1988.

(2) 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, § 4072(h), Dec. 22, 1987, 101 Stat. 1339–120, provided that: "The amendment made by this section shall not become effective until after such report is submitted to the Congress later than April 1, 1993."
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 1395–3 of this title, see section 4294(a) of Pub. L. 100–233, as amended, set out as an Effective Date note under section 1395–3 of this title.

**Effective Date of 1986 Amendment**

Pub. L. 99–509, title IX, §9335(c)(4), Oct. 21, 1986, 100 Stat. 509, 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).”


Amendment by section 9337(d) 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.


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. 99–272, title IX, §9107(c)(2), Apr. 7, 1986, 100 Stat. 162, 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, §9101(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. 99–272].”

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.”


**Effective Date of 1983 Amendment**


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)] 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)] 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 1395z 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(c) 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 2325(b) of Pub. L. 98–369 effective July 18, 1984, see section 2325(g) of Pub. L. 98–369, set out as a note under section 1395f of this title.


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)(19)–(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 1395ww 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 arrangement 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, see section 97–249, except that this amendment relates, see section 309(c)(1) of Pub. L. 97–448, set out as a note under section 426 of this title.
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, §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 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 cost reporting periods beginning on or after the date of the enactment of this Act [Sept. 3, 1982]."

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 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 1395cc of this title.


"(1) Any amendment to the Omnibus Budget 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 1395gg of this title] 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 title 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 1396u, 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.

Amendment by section 212(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 212(d) of Pub. L. 97–35, set out as a note under section 1395a of this title.


"(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."


"(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."


"(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.

Amendment by Pub. L. 98–21, title VI, §605(a), Apr. 20, 1983, 97 Stat. 169, 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 enactment [April 20, 1983]."

Pub. L. 97–248, title I, §101(c)(3), Sept. 3, 1982, 96 Stat. 344, as amended by Pub. L. 96–499, title IX, §930(c)(3), Dec. 5, 1980, 94 Stat. 2614, provided that: "The amendments made by this section [amending this section and sections 1396u, 1395bb, 1395cc, and 1395gg of this title] shall become effective on the date of enactment [probably should be "on"] which final regulations, promulgated 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]."


"(1) the amendments made by this section [amending this section, sections 426, 1395c, 1395d, 1395f, 1395h, 1395k, 1395n, and 1395n of this title, and section 231f of Title 45, Railroads, and repealing section 1395m of this title] are first issued; and

"(2) such regulations shall be issued not later than the first day of the eleventh month following the month in which this Act is enacted [December 1980]."
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 1396k 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 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 1396k 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 1396f of this title.


"The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 1981."


Amendment by section 936(c)–(e) of Pub. L. 96–499 effective with respect to a facility’s or provider’s first accounting period beginning on or after January 1, 1981.


"Amendment by section 936(c)(2) of Pub. L. 96–499 applicable with respect to services furnished on or after July 1, 1981, see section 936(d) of Pub. L. 96–499, set out as a note under section 1396f of this title."

Effective Date of 1975 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 1396f of this title.

Pub. L. 92–603, title II, §223(b), Oct. 31, 1972, 86 Stat. 1394, provided that: "The amendments made by this section [amending this section and sections 1395f, 1395l, 1395n, 1395cc of this title] shall become effective with respect to accounting periods beginning after December 31, 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 1361(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, §254(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]."

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, §257(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, 1972."

Amendment by section 256(a) of Pub. L. 92–603 to apply with respect to services rendered after Dec. 31, 1972, see section 256(c) of Pub. L. 92–603, set out as a note under section 1395f of this title.

**Effective Date of 1968 Amendment**

Pub. L. 90–248, title I, §127(c), Jan. 2, 1968, 81 Stat. 847, 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 section (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)."


**Construction of 2008 Amendment**


**Implementation**

Pub. L. 116–260, div. CC, title I, §117(c), Dec. 27, 2020, 134 Stat. 2950, provided that: "Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendment made by subsection (a) [amending this section] by interim final rule, program instruction, or otherwise."

Conforming References to Previous Part D


**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 1396u of this title.

**Frontier Extended Stay Clinic Demonstration Project**


"(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 term ‘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


“(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. 1395 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 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)) who is certified as a registered nurse first assistant by an organization recognized by the Secretary.

“(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 in the State in which the surgical first assisting services are performed;

“(B) has completed a minimum of 2,000 hours of training in the care of the typical patient, including the care of typical among eligible beneficiaries; and

“(C) is certified as a registered nurse first assistant by an organization recognized by the Secretary.

“STUDIES RELATING TO VISION IMPAIRMENTS


“(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 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


“(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;

“(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(s)(5) of the Social Security Act (42 U.S.C. 1395x(s)(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 chiropractors, 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.

(1) Demonstration Projects.—

(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) Evaluation and Report.—The Secretary shall conduct an evaluation of the demonstration projects.

(B) Duration.—The Secretary shall implement the demonstration projects by October 1, 2004.

(3) Evaluation and Report.—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 satisfiability 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.

(4) 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 legislation or administrative action as the Secretary determines are appropriate.

(5) 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.

(6) Funding.—

(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 1811 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 were not implemented.

(2) Evaluation and Report.—There are authorized to be appropriated such sums as are necessary for the purposes of developing and submitting the report to Congress under subsection (d).

Demonstration Project to Clarify the Definition of Homebound


(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. 1395 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 increased the costs of home health services under the medicare program.

(2) The specific data evidencing the amount of any increase in expenditures that is 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.
“(b) 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 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.

“(1) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplemental Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395x).

“(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. 1395x).

“(2) HOME HEALTH SERVICES.—The term ‘home health services’ means furnishing, during any given 30-month period under this section, sections 1395r and 1395fff of this title, and amendments made by this section [amending this section (amending this section and sections 1395x of this title)].

In this section:

“(1) 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


“(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 1395x 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)(v)(I) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(v)(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 42926–42930).

“(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)(v)(I) of such Act (42 U.S.C. 1395x(v)(1)(L)(v)(I)) 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 106.56, 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 42926–42930).”

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 1395x and 1395fff 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 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, § 439], 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 Comptroller 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.—
TITLE 42—THE PUBLIC HEALTH AND WELFARE

§1395x

“(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


“(a) DEVELOPMENT.—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.

“(b) 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.

“(c) 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.].

“(d) 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, §4109(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, §4109(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 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. 1395 et seq.], in cases in which a subluxation has not been demonstrated by X-ray to exist.”
**Title 42—The Public Health and Welfare**

### §1395x 

**Authorizing Payment for Paramedic Intercept Service Providers in Rural Communities**

Pub. L. 105-33, title IV, §4531(c), Aug. 5, 1997, 111 Stat. 462, as amended by Pub. L. 106-113, div. B, §1006(a)(6) [title IV, §412(a)], Nov. 29, 1999, 113 Stat. 1501A-377, provided that: “In promulgating regulations to carry out section 186l(v)(1)(L) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)) 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 or an organization authorized by the state to provide ambulance services on a voluntary basis solely 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 program described in section 1861(v)(1)(L)(ii) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(ii))
   - (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)).

### §601(b)(2), Nov. 10, 1998, 112 Stat. 3286, directed Secretary of Health and Human Services to conduct a study analyzing effects of coverage of osteoporosis drugs under part B of such program and utilization of inpatient hospital and extended care services by such individuals, and, by not later than Oct. 1, 1999, 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.

### §4531(c), Aug. 5, 1997, 111 Stat. 462, as amended by Pub. L. 103-432, title I, §160(d)(4), 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 Secretary to submit to Congress by not later than Apr. 1, 1999, 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.

### §4207(d)(2), formerly §4207(c), 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).’’

### §4601(b), Nov. 5, 1990, 104 Stat. 1388-61, as amended by 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 Secretary 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.

### §4156(b), Nov. 5, 1990, 104 Stat. 1388-77, as amended by 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 Secretary 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.
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 §4207(d)(3), Nov. 5, 1990, 104 Stat. 1388–121, as renumbered by Pub. L. 106–422, title I, §108(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 the date on which the Act is effective; (2) for cost reporting periods beginning on or after July 1, 1992, a combined area wage index consisting of 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 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 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, §6205, 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 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. 2167, 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 demonstrates 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.” 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 clinic [Nov. 10, 1988], 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 that the services of a physician assistant or nurse practitioner be provided in the facility.” 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(e)(7) of the Social Security Act [42 U.S.C. 1395x(e)(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(l)(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. 1395l–3(c)(3)(A)] (as added by section 4203(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., 1395 et seq.) at any time prior to six months after the date on which the Congress receives the report required under section 9365(k)(4) of the Omnibus Budget Reconciliation Act of 1986 [section 9365(k)(4) of Pub. L. 99–509, set out below]."

**DELAY IN PUBLISHING REGULATIONS WITH RESPECT TO DETERMINING 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. 1395(u)]) for purposes of section 1861(v)(1)(L) of the Social Security Act [42 U.S.C. 1395x(u)], for periods beginning on or 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, § 9005(b), Oct. 21, 1986, 100 Stat. 1993, 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, § 9005(k), Oct. 21, 1986, 100 Stat. 1994, directed Secretary of Health and Human Services to conduct a demonstration program concerning prior and concurrent authorization of post-hospital services to include at least four projects and 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, 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**


‘‘(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 that 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, § 9015(c), Oct. 21, 1986, 100 Stat. 2006, directed Comptroller General to study and report to Congress, not later than Feb. 1, 1988, on appropriate-ness 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**


**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. 1983, 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 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 122 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. 1985, 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. (d)(2)(A)(ii)(I) of this section and report results of such study to Congress with respect to the report required under section 1922(1)(A) [122][2](I) 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
ELIMINATION OF PRIVATE ROOM SUBSIDY


"(a) The Secretary of Health and Human Services shall...keep such payments required under 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 this section] 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


"(1) on July 1, 1977, was operating and located in an area which on that date (A) was not an...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."

PROCLAMATION OF REGULATIONS DEFINING COSTS CHARGEABLE TO PERSONAL FUNDS OF PATIENTS IN SKILLED NURSING FACILITIES; DATE OF ISSUANCE

cians in such hospital agree not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by title [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) would, except for the provisions of this section, be applicable) in like manner as if the 'December 31, 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 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, §246(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 1881(a)(6) of the Social Security Act [42 U.S.C. 1395x(a)(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 applicable under section 1853 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."

Executive Documents

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 they do not experience the care and love that a friend or family member can provide. Sometimes, circumstances or medical treatments prevent the patient’s family from being there for them. Members of religious orders are sometimes unable to choose someone other than an immediate family member to visit and make medical decisions on their behalf. Also uniquely affected are gay and lesbian Americans who are often barred from the bedside of the partners with whom they may have shared 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’ needs. It means that a family’s medical decisions may be made in levels of care and 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.

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. 1395c and other relevant provisions of law, and provide technical assistance to 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 item or 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(yy)(3) 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 part B 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 other disease screening 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);

(5) which are required as a result of war, or of an act of war, occurring after the effective date of such individual’s current coverage under such part;

(6) which constitute personal comfort items (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear

\(^1\) See References in Text note below.