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

(b) Model electronic complaint form

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

(c) Annual reports by the Secretary

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

(d) Definitions

In this section:

(1) MA–PD plan

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

(2) Prescription drug plan

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

(3) Secretary

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

(4) System

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


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

AMENDMENTS


§ 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 of this subchapter, 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) of this section.

(b) Inpatient hospital services

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

(1) bed and board;

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

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

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K) of this section, 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 Dental Education of the American Dental 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 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 sub-
chapter.

c) Inpatient psychiatric hospital services

The term “inpatient psychiatric hospital serv-
ices” means inpatient hospital services fur-
nished to an inpatient of a psychiatric hospital.

d) Supplier

The term “supplier” means, unless the con-
text 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 inpa-
tients (A) diagnostic services and therapeutic
services for medical diagnosis, treatment, and
care of injured, disabled, or sick persons, or
(B) rehabilitation services for the rehabilita-
tion 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 (ss)(1) of this section) 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 require-
ment 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 profes-
sional nurse must be present on the premises
to render or supervise the nursing service pro-
vided, 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 qua-
lify as a hospital would seriously reduce the
availability of such services to such individu-
als, and

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

(6)(A) has in effect a hospital utilization re-
view plan which meets the requirements of
subsection (k) of this section and (B) has in
place a discharge planning process that meets
the requirements of subsection (ee) of this sec-
tion;

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

(8) has in effect an overall plan and budget
that meets the requirements of subsection (s)
of this section; 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) of this section,
such term includes any institution which meets
the requirements of paragraph (1) of this sub-
section. For purposes of sections 1395f(d) and
1395n(b) of this title (including determination of
whether an individual received inpatient hos-
pital services or diagnostic services for purposes
of such sections), section 1395f(f)(2) of this title,
and subsection (i) of this section, such term in-
cludes any institution which (I) meets the re-
quirements of paragraphs (5) and (7) of this sub-
section, (ii) is not primarily engaged in provid-
ing the services described in subsection (j)(1)(A)
of this section and (iii) is primarily engaged in
providing, by or under the supervision of indi-
viduals referred to in paragraph (1) of subsection
r of this section, to inpatients diagnostic serv-
ces and therapeutic services for medical diag-
nosis, treatment, and care of injured, disabled,
or sick persons, or rehabilitation services for
the rehabilitation of injured, disabled, or sick
persons. For purposes of section 1395f(f)(1) of this
title, such term includes an institution which (i)
is a hospital for purposes of sections 1395f(d),
1395f(f)(2), and 1395n(b) of this title and (ii) is ac-
credited by a national accreditation body recog-
nized by the Secretary under section 1395b(b) of
this title, or is accredited by or approved by a
program of the country in which such institu-
tion is located if the Secretary finds the accredi-
tation or comparable approval standards of such
program to be essentially equivalent to those of
such a national accreditation body.. Notwith-
standing the preceding provisions of this sub-
section, such term shall not, except for purposes
of subsection (a)(2) of this section, include any
institution which is primarily for the care and
treatment of mental diseases unless it is a psy-
chiatric hospital (as defined in subsection (f)
of this section). The term “hospital” also includes
a religious nonmedical health care institu-
tion (as defined in subsection (ss)(1) of this section),
but only with respect to items and services ordi-
narily furnished by such institution to inpa-
tients, 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 re-
requirements otherwise applicable) as may be pro-

1So in original.
vided in regulations consistent with section 1395i–5 of this title. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1395bcb 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 requirements take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which such facility is located, and the scope of services rendered by such facility; and the Secretary, by regulations, shall provide for the continued participation of such a facility where such personnel requirements are not fully met, for such period as the Secretary determines that (i) the facility is making good faith efforts to fully comply with the personnel requirements, (ii) the employment by the facility of such personnel as are available to the facility will not adversely affect the health and safety of patients, and (iii) if the Secretary has determined that because of the facility’s waiver under this subparagraph the facility should limit its scope of services in order not to adversely affect the health and safety of the facility’s patients, the facility is so limiting the scope of services it provides; and

(C) with respect to the fire and safety requirements promulgated under paragraph (9), the Secretary 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 (i) may accept a facility’s compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients. The term “hospital” does not include, unless the context otherwise requires, a critical access hospital (as defined in subsection (mm)(1) of this section).

(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) of this section;

(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 of this subchapter; and

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

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

(g) Outpatient occupational therapy services

The term “outpatient occupational therapy services” has the meaning given the term “outpatient physical therapy services” in subsection (p) of this title, 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 (i) of this section), under a teaching program of such hospital approved as provided in the last sentence of subsection (b) of this section, 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 pro-
vided 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) of this section 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 after 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 such hospital; and an individual shall be deemed to have been 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 such hospital; and an individual shall be deemed to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

(j) Skilled nursing facility

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

(k) Utilization review

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

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

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

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continu-

ous 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 of this chapter are superior in their effectiveness to the procedures required under this section, he may, to the extent that he deems it appropriate, require for purposes of this subchapter that the procedures established pursuant to subchapter XIX of this chapter be utilized instead of the procedures required by this section.

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

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

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

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

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

(m) Home health services

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

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

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

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

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

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

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

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

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

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A), but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) of this section if furnished to an inpatient of a hospital. 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 circumstances when the need for additional care is finite and predictable).

(n) Durable medical equipment

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

(o) Home health agency

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

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

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

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing;
(5) has in effect an overall plan and budget that meets the requirements of subsection (2) of this section;

(6) meets the conditions of participation specified in section 1395b(bb)(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) effective for a period of 4 years (as specified by the Secretary) or in the case of a change in the ownership or control of the agency (as determined by the Secretary) during or after such 4-year period, an additional period of time that the Secretary determines appropriate, such additional period not to exceed 4 years from the date of such change in ownership or control; and

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

(C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of $60,000 or 10 percent of the aggregate amount of payments to the agency under this subchapter and subchapter XIX of this chapter for that year, as estimated by the Secretary that the Secretary determines is commensurate with the volume of the billing of the home health agency; and

(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 of this subchapter 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) of this section), 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) of this section if furnished to an inpatient of a hospital; and

(4) any such service—

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

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

(ii) has policies, established by a group of professional personnel, including one or more physicians (associated with the clinic or rehabilitation agency) and one or more qualified physical therapists, to govern the services (referred to in clause (i)) it provides,

(iii) maintains clinical records on all patients,

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

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

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

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

(q) Physicians' services

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

(r) Physician

The term ‘physician’, when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1301(a)(7) of this title), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsection (p), (m), (p)(1), and (s) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) of this section and with respect to the provision of items or services described in subsection (s) of this section which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (6) a doctor of veterinary medicine, (7) a dentist, (8) a doctor of dental surgery or of dental medicine who is legally authorized to perform as a doctor of dental surgery by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (9) a doctor of medicine or osteopathy who is legally authorized to practice medicine and surgery by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (10) a doctor of veterinary medicine who is legally authorized to practice veterinary medicine by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (11) a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2) of this section), and such services and supplies furnished as an incident to such clinical psychologist's services, and such services and supplies furnished as an incident to such 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; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm of this title to a member of an eligible organization by a clinical psychologist or by a clinical social worker (as defined in subsection (hh)(2) of this section), 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.

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2) of this section), 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) services furnished pursuant to a risk-sharing contract under section 1395mm of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2) of this section), 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) services furnished pursuant to a risk-sharing contract under section 1395mm of this title to a member of an eligible organization by a clinical psychologist or by a clinical social worker (as defined in subsection (hh)(2) of this section), 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) services furnished pursuant to a risk-sharing contract under section 1395mm of this title to a member of an eligible organization by a clinical psychologist or by a clinical social worker (as defined in subsection (hh)(2) of this section), 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) services furnished pursuant to a risk-sharing contract under section 1395mm of this title to a member of an eligible organization by a clinical psychologist or by a clinical social worker (as defined in subsection (hh)(2) of this section), 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.
(K)(i) services which would be physicians’ services and services described in subsections (ww)(1) and (hhh) of this section if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a physician assistant (as defined in subsection (aa)(5) of this section) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician’s professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,\textsuperscript{2}

(ii) services which would be physicians’ services and services described in subsections (ww)(1) and (hhh) of this section if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5) of this section) working in collaborating practice (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) 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) of this section);

(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) of this section);

(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) of this section); and\textsuperscript{3}

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

(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 (vv)(1) of this section) in the case of a beneficiary with diabetes or a renal disease who—

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

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

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

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

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

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

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

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

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

(Y) diabetes screening tests (as defined in subsection (yy) of this section); and

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

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) 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)); and

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

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

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\textsuperscript{2}So in original. Probably should be followed by “and”.

\textsuperscript{3}So in original. The word “and” probably should not appear.
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(FF) personalized prevention plan services (as defined in subsection (hhh));

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

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

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

(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 podiatrist 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) of this section);

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

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

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

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

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

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

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) of this section 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.

(6) Drugs and biologicals

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

(2)(A) For purposes of paragraph (1), the term "drugs" also includes any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication (as described in subparagraph (B)).
(B) In subparagraph (A), the term "medically accepted indication", with respect to the use of a drug, includes any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if—

(i) the drug has been approved by the Food and Drug Administration; and
  
(ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or
  
(II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

The Secretary may revise the list of compendia in clause (ii)(I) as is appropriate for identifying medically accepted indications for drugs. On and after January 1, 2010, no compendia may be included on the list of compendia under this subparagraph unless the compendia 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, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1395f(g) and section 1395m(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 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 of this subchapter, but only if—
  
(I) payment for such services as furnished under such arrangement would be made under part B of this subchapter 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,

(ii) for which payment may be made under part B of this subchapter, 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) of this section or for which...
entitlement exists by reason of clause (II) of section 1395k(a)(2)(B)(i) of this title, and (ii) such hospital (or medical school under arrangement with such hospital) incurs no actual cost in the furnishing of such services, the reasonable cost of such services shall (under regulations of the Secretary) be deemed to be the cost such hospital or medical school would have incurred had it paid a salary to such physicians rendering such services approximately equivalent to the average salary paid to all physicians employed by such hospital (or if such employment does not exist, or is minimal in such hospital, by similar hospitals in a geographic area of 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 this chapter (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 chapter (not otherwise included in the computation of such State rates), if the Secretary finds that such rates are reasonably related to (but not necessarily limited to) analyses undertaken by such State of costs of care in comparable facilities in such State. Notwithstanding the previous sentence, such regulations with respect to skilled nursing facilities shall take into account (in a manner consistent with subparagraph (A) and based on patient-days of services furnished) the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this subchapter) of such facilities complying with the requirements of subsections (b), (c), and (d) of section 1395l–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 control and peer review organization (or, in the absence of such a qualified organization, the Secretary or such agent as the Secretary may designate) determines that inpatient hospital services for the individual are not medically necessary but post-hospital extended care services for the individual are medically necessary and such extended care services are not otherwise available to the individual (as determined in accordance with criteria established by the Secretary) at the time of such determination, payment for such services provided to the individual shall continue to be made under this subchapter at the payment rate described in clause (ii) during the period in which—

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

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

(III) the individual is entitled to have payment made for post-hospital extended care services under this subchapter, except that if the Secretary determines that there is not an excess of hospital beds in such hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital, such payment shall be made (during such period) on the basis of the amount otherwise payable under part A with respect to inpatient hospital services.

(ii) Except as provided in subclause (I), 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 of this title 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 of this chapter, 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 subchapter shall, for purposes of this chapter (other than this subchapter), 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 (a)(7) of this section and the financial security requirement described in subsection (b)(8) of this section;

(ii) in the case of home health agencies to which the surety bond requirement described in subsection (a)(7) of this section apply, any costs attributed to interest charged such an agency in connection with amounts borrowed by the
agency to repay overpayments made under this subchapter to the agency, except that such costs may be included in reasonable cost if the Secretary determines that the agency was acting in good faith in borrowing the amounts; (iii) in the case of contracts entered into by a home health agency after December 5, 1980, for the purpose of having services furnished for or on behalf of such agency, any cost incurred by such agency pursuant to any such contract which is entered into for a period exceeding five years; and (iv) in the case of contracts entered into by a home health agency 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 determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

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

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

The Secretary shall prescribe in regulation criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontractors 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 reasonably related to the charges for services provided on an outpatient basis by hospitals (other than bona fide emergency services as defined in clause (ii)) or clinics (other than rural health clinics), which are reimbursed on a cost basis or on the basis of cost-related charges, and by physicians utilizing such outpatient facilities. Such limitations shall be reasonably related to the charges in the same area for similar services provided in 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 provided in a hospital emergency room after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(I) plating the patient's health in serious jeopardy; (II) serious impairment to bodily functions; or (III) serious dysfunction of any bodily organ or part.

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

(I) July 1, 1985, and before July 1, 1986, 120 percent of the mean of the labor-related and nonlabor per visit costs for freestanding home health agencies, (II) July 1, 1986, and before July 1, 1987, 115 percent of such mean, (III) July 1, 1987, and before October 1, 1997, 112 percent of such mean, (IV) October 1, 1997, and before October 1, 1998, 105 percent of the median of the labor-related and nonlabor per visit costs for freestanding home health agencies, or (V) October 1, 1998, 106 percent of such median.

(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis. The Secretary may provide for such exceptions and limitations on such discipline 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 (vii), 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 clause (vii) and clause (viii), the per beneficiary limitation shall be equal to the median of these limits (or the Secretary’s best estimates thereof) applied to other home health agencies as determined by the Secretary. A home health agency that has altered its corporate structure or name shall not be considered a new provider for this purpose.

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

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

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

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

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

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

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

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

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

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

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

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

(O)(1) 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 (ii), 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 costs 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 costs, costs incurred by a provider of services representing a beneficiary in an unsuccessful appeal of a determination described in section 1395f(b) of this title shall not be allowable as reasonable costs.

(S)(i) Such regulations shall not include provisions 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 1395(a)(2)(B)(i)(I) of this title by 5.8 percent for payments attributable to portions of cost reporting periods occurring during fiscal years 1991 through 1999 and until the first date that the prospective payment system under section 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) of this section).

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

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

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

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

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

(iv) for cost reporting periods beginning during a subsequent fiscal year, by 30 percent of such amount otherwise allowable.

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

(V) In determining such reasonable costs for skilled nursing facilities with respect to cost reporting periods beginning on or after October 1, 2005, the amount of bad debts otherwise treated as allowed costs which are attributable to the coinsurance amounts under this subchapter for individuals who are entitled to benefits under part A and—

(i) are not described in section 1396a–5(c)(6)(A)(ii) of this title shall be reduced by 30 percent of such amount otherwise allowable; and

(ii) are described in such section shall not be reduced.

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

(B) Where a provider of services which has an agreement in effect under this subchapter furnishes to an individual items or services which are in excess of or more expensive than the items or services with respect to which payment may be made under part A or part B of this subchapter, as the case may be, the Secretary shall take into account for purposes of payment to such provider of services only the items or services with respect to which such payment may be made.

(3) If the bed and board furnished as part of inpatient hospital services (including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services is in accommodations more expensive than semi-private accommodations, the amount taken into account for purposes of payment under this subchapter with respect to such bed and board under part A of this subchapter 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) 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) of this section (including through the operation of subsection (g) of this 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) of this section 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 rou-

1See References in Text note below.
tine 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 of this chapter, by a quality control and peer review organization designated for the area in which such hospital or critical access hospital is located shall be deemed to have been conducted pursuant to arrangements between such hospital or critical access hospital and such organization under which such hospital or critical access hospital is obligated to pay to such organization, as a condition of receiving payment for hospital or critical access hospital services so furnished under this part or under such a State plan, such amount as is reasonably incurred and requested (as determined under regulations of the Secretary) by such organization in conducting such review activities with respect to services furnished by such hospital or critical access hospital to such patients.

(x) State and United States

The terms “State” and “United States” have the meaning given to them by subsections (h) and (i), respectively, of section 1413 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 (aa)(1) of this section), but only (except for purposes of subsection (a)(2) of this section) 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 1395ii–6 of this title.

(2) Notwithstanding any other provision of this subchapter, payment under part A of this subchapter 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 of this subchapter may not be made for post-hospital extended care services—

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

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

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

(3) The amount payable under part A of this subchapter 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 1395a(a)(3) of this title).

(4) For purposes of subsection (d) of this section, 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.

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

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

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

(D) 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) of this section if furnished as an incident to a physician’s professional service and items and services described in subsection (s)(10) of this section,

(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) of this section), and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician’s service, and

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

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

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

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

(C) maintains clinical records on all patients;

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

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

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

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

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

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

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

(K) meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic.
For the purposes of this subchapter, such term includes only a facility which (i) is located in an area that is not an urbanized area (as defined by the Bureau of the Census) and in which there are insufficient numbers of needed health care practitioners (as determined by the Secretary), and that, within the previous 4-year period, has been designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services or designated by the Secretary either (I) as an area with a shortage of personal health services under section 330(b)(3) or 1302(7) of the Public Health Service Act [42 U.S.C. 254b(b)(3), 300e–1(7)], (II) as a health professional shortage area described in section 332(a)(1)(A) of that Act [42 U.S.C. 254e(a)(1)(A)] because of its shortage of primary medical care manpower, (III) as a high impact area described in section 329(a)(5) of that Act, or (IV) as an area which includes a population group which the Secretary determines has a health manpower shortage under section 332(a)(1)(B) of that Act [42 U.S.C. 254e(a)(1)(B)], (ii) has filed an agreement with the Secretary by which it agrees not to charge any individual or other person for items or services for which such individual is entitled to have payment made under this subchapter, except for the amount of any deductible or coinsurance amount imposed with respect to such items or services (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1395f 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 of this chapter and that subsequently fails to satisfy the requirement of clause (i) shall be considered, for purposes of this subchapter and subchapter XIX of this chapter, 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 (d)(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) 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 of this subchapter, 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. 450f et seq.] or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

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

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

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

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

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

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

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

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

(bb) Services of a certified registered nurse anesthetist

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

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

(cc) Comprehensive outpatient rehabilitation facility services

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

(A) physicians' services;

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

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

(D) social and psychological services;

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

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

(G) supplies and durable medical equipment; and

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

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

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

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

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

(C) maintains clinical records on all patients;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(F) physicians’ services,

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

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

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

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

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

(A)(i) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1395(d) of this title,

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

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

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

(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1395(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) of this section),

(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) of this section) or nurse practitioner (as defined in subsection (aa)(5) of this section), 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
granting of any subsequent waiver request should such a waiver again become necessary. Paragraph (A) or (C) shall not preclude the Secretary. The granting of a waiver under sub-
paragraph (A) or (C), shall be deemed to be granted unless such re-
organization under subparagraph (A) or (C), required and which is requested by an agency or organization with respect to all or part of the nursing care described in paragraph (1)(A) if such agency or organization—
(i) is located in an area which is not an urbanized area (as defined by the Bureau of the Census);
(ii) was in operation on or before January 1, 1983; and
(iii) has demonstrated a good faith effort (as determined by the Secretary) to hire a sufficient number of nurses to provide such nursing care directly.

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

(C) The Secretary may waive the requirements of paragraph (2)(A)(i)(I) for an agency or organization with respect to the services 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 Census), and
(ii) demonstrates to the satisfaction of the Secretary that the agency or organization has been unable, despite diligent efforts, to recruit appropriate personnel.

(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (A) if the arrangements are necessary to ensure a timely and smooth transition to the most appropriate type of and setting for post-hospital or rehabilitative care. The guidelines and standards shall include the following:

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

(B) Hospitals must provide a discharge planning evaluation for patients identified under subparagraph (A) and for other patients upon 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 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).

(E) 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 extended care 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),

(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(c)(1) of the Public Health Service Act [42 U.S.C. 300x–2(c)(1)]; or

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

(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 1913(c)(1) of the Public Health Service Act [42 U.S.C. 300x–2(c)(1)].

(gg) Certified nurse-midwife services

(1) The term "certified nurse-midwife services" means such services furnished by a certified nurse-midwife (as defined in paragraph (2)) and such services and supplies furnished as an incident to the nurse-midwife's service which the certified nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) as would otherwise be covered if furnished by a physician or as an incident to a physicians' service.

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

(hh) Clinical social worker; clinical social worker services

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

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

(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and
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(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 services furnished as an incident to his service furnished by a qualified 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—
(I) the individual's attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and
(II) the individual is confined to the individual’s home (except when receiving items and services referred to in subsection (m)(7) of this section).

(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 speech-language pathologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master’s or doctoral degree in speech-language pathology or a related field, and successfully completed a national examination in speech-language pathology approved by the Secretary.

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

(i) is licensed as an audiologist by the State in which the individual furnishes such services, or
(ii) in the case of an individual who furnishes services in a State which does not license audiologists, has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating such supervised clinical experience), performed not less than 9 months of supervised full-time audiology services after obtaining a master's or doctoral degree in audiology or a related field, and successfully completed a national examination in audiology approved by the Secretary.

(mm) Critical access hospital; critical access hospital services

(1) The term “critical access hospital” means a facility certified by the Secretary as a critical
access hospital under section 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 by a hospital.

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

(nn) Screening pap smear; screening pelvic exam

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

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

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

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

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

(oo) Prostate cancer screening tests

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

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

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

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

(pp) Colorectal cancer screening tests

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

(A) 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.
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.

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.

(2) The term "religious nonmedical health care institution" means an institution that is

(A) described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of such section;
(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;
(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;
(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;
(E) provides such nonmedical items and services to inpatients on a 24-hour basis;
(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;
(G) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;
(H) 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 for 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 of this subchapter 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 of this subchapter, 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 of this subchapter, 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 1861-(3a)(1) of this title or subsection (y)(1) of this section 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 medical nutrition therapy services are performed.

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

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

(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,9 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) and end-of-life planning (as defined in paragraph (3)) upon the agreement with the individual, 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)(1).

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

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

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

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

(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).

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

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

(M) An electrocardiogram.

(N) Additional preventive services (as defined in subsection (dd)).

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

9So in original. Probably should be “weight, body mass index.”.
(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.

(xx) Cardiovascular screening blood test

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

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

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

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the United States Preventive Services Task Force.

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

(yy) Diabetes screening tests

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

(A) a fasting plasma glucose test; and

(B) such other tests, and modifications to 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/m$^2$.

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

(E) Previous identification of impaired glucose tolerance.

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

(i) Overweight, defined as a body mass index greater than 25, but less than 30, kg/m$^2$.

(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) of this section), 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 1395–5 of this title.

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

(i) in a year insofar as such payments exceed $700,000; and

(ii) after December 31, 2006.

(bbb) Ultrasound screening for abdominal aortic aneurysm

The term "ultrasound screening for abdominal aortic aneurysm" means—

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

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

(ccc) Long-term care hospital

The term "long-term care hospital" means a hospital which—

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

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

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

(4) meets the following facility criteria:

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

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

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

(ddd) Additional preventive services; preventive services

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

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

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

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

(2) In making determinations under paragraph (1) regarding the coverage of a new service, the Secretary shall use the process for making national coverage determinations (as defined in section 1395ff(f)(1)(B) of this title) under this subchapter. As part of the use of such process, the Secretary may conduct an assessment of the relation between predicted outcomes and the expected 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 services described in subparagraph (M) of such subsection).

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

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

(eee) Cardiac rehabilitation program; intensive cardiac rehabilitation program

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

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

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

(i) in a physician’s office;

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

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

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

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

(i) the individual’s diagnosis;

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

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

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

(A) physician-prescribed exercise;

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

(C) psychosocial assessment;

(D) outcomes assessment; and

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

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

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

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

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

(i) one or more of the following:

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

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

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

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

(I) low density lipoprotein;
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(II) triglycerides;
(III) body mass index;
(IV) systolic blood pressure;
(V) diastolic blood pressure; or
(VI) the need for cholesterol, blood pressure, and diabetes medications.

(B) To be eligible for an intensive cardiac rehabilitation program, an individual must have—
   (i) had an acute myocardial infarction within the preceding 12 months;
   (ii) had coronary bypass surgery;
   (iii) stable angina pectoris;
   (iv) had heart valve repair or replacement;
   (v) had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
   (vi) 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)(5) of this title), up to 6 sessions per day, over a period of up to 18 weeks.

(5) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with cardiac pathophysiology who is licensed to practice medicine in the State in which a cardiac rehabilitation program (or the intensive cardiac rehabilitation program, as the case may be) is offered—
   (A) is responsible for such program; and
   (B) in consultation with appropriate staff, is involved substantially in directing the progress of individual patient in the program.

(fff) Pulmonary rehabilitation program

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

(2) The items and services described in this paragraph are—
   (A) physician-prescribed exercise;
   (B) education or training (to the extent the education or training is closely and clearly related to the individual’s care and treatment and is tailored to such individual’s needs);
   (C) psychosocial assessment;
   (D) outcomes assessment; and
   (E) such other items and services as the Secretary may determine, but only if such items and services are—
      (i) reasonable and necessary for the diagnosis or active treatment of the individual’s condition;
      (ii) reasonably expected to improve or maintain the individual’s condition and functional level; and
      (iii) furnished under such guidelines relating to the frequency and duration of such items and services as the Secretary shall establish, taking into account accepted norms of medical practice and the reasonable expectation of improvement of the individual.

(3) The Secretary shall establish standards to ensure that a physician with expertise in the management of individuals with respiratory

(ggg) Kidney disease education services

(1) The term “kidney disease education services” means educational services that are—
   (A) furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, will require dialysis or a kidney transplant;
   (B) furnished, upon the referral of the physician managing the individual’s kidney condition, by a qualified person (as defined in paragraph (2)); and
   (C) designed—
      (i) to provide comprehensive information (consistent with the standards set under paragraph (3)) regarding—
         (I) the management of comorbidities, including for purposes of delaying the need for dialysis;
         (II) the prevention of uremic complications; and
         (III) each option for renal replacement therapy (including hemodialysis and peritoneal dialysis at home and in-center as well as vascular access options and transplantation);
      (ii) to ensure that the individual has the opportunity to actively participate in the choice of therapy; and
      (iii) to be tailored to meet the needs of the individual involved.

(2)(A) The term “qualified person” means—
      (i) a physician (as defined in subsection (r)(1)) or a physician assistant, nurse practitioner, or clinical nurse specialist (as defined in subsection (aa)(5)), who furnishes services for which payment may be made under the fee schedule established under section 1395w-4 of this title; and
      (ii) a provider of services located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(B) Such term does not include a provider of services (other than a provider of services described in subparagraph (A)(i)) 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.

10So in original.
(hh) Annual wellness visit

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

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

(B) that—

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

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

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

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

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

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

(D) Detection of any cognitive impairment.

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

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

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

(F) The furnishing of personalized health advice and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

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

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

(A) a physician;

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

(C) Any other 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 300g–12(f) of this title as part of the requirement to develop a personalized prevention plan to comply with this subparagraph.

(C) 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.

(D) 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

REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in text, are classified to section 1395 et seq. and section 1395j et seq., respectively, of this title.

Section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (s)(10)(A), is section 4072(b) of Pub. L. 100–203, which is set out as a note below. The Public Health Service Act, referred to in subsec. (v)(13)(A), 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 (§ 300g 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.


Part B of subchapter XI of this chapter, referred to in subsec. (w)(2), is classified to section 1320c et seq. of this title.

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 254a of this title and was omitted in the general amendment of subpart I (§ 254b et seq.) of part D of subchapter II of chapter 6A of this title by Pub. L. 104–299, § 2, Oct. 11, 1996, 110 Stat. 3626.

The Indian Self-Determination Act, referred to in subsec. (aa)(4)(D), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2306, which is classified principally to part A (§ 450 et seq.) of subchapter II of chapter 14 of Title 25. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.


AMENDMENTS

2010—Subsec. (aa)(3)(A). Pub. L. 111–148, § 10501(1)(D)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: “services of the type described in subparagraphs (A) through (C) of paragraph (1) and services described in subsections (qq) and (vv); and”.


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

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


Subsec. (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 or personalized prevention plan services during the period of 12 months after the date that the beneficiary’s coverage begins under part B of this subchapter and shall be eligible to receive personalized prevention plan services under this subsection provided that the beneficiary has not received such services within the preceding 12-month period.”

“(ii) The Secretary shall establish procedures to make beneficiaries aware of the option to select an initial preventive physical examination or personalized prevention plan services during the period of 12 months after the date that a beneficiary’s coverage begins under part B of this subchapter, which shall include information regarding any relevant differences between such services.”

2008—Subsec. (e). Pub. L. 110–275, § 125(b)(2), in third sentence after par. (9), substituted “and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1386b(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 that the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.” for “and (ii) is accredited by the Joint Commission on Accreditation of Hospitals, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of the Joint Commission on Accreditation of Hospitals”.

Subsec. (p). Pub. L. 110–275, § 143(b)(5), struck out third sentence in concluding provisions, which read as follows: “The term ‘outpatient physical therapy services’ also includes speech-language pathology services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient, subject to the conditions prescribed in this subpar.”

Subsec. (q)(2)(D). Pub. L. 110–275, § 143(b)(6), inserted “, outpatient speech-language pathology services,” after “physical therapy services”.

Subsec. (s)(2)(F). Pub. L. 110–275, § 153(b)(3)(B), inserted “, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1395rr(b)(14)(B) of this title)” before semicolon at end.

Subsec. (s)(2)(CC), (DD). Pub. L. 110–275, §144(a)(1)(A), added subpars. (CC) and (DD).
Subsec. (t)(2)(B). Pub. L. 110–275, §182(b), in concluding provisions, inserted “On and after January 1, 2010, no compendia may be included on the list of compendia under contract with the center” after “outpatient of a

Subsec. (aa)(3). Pub. L. 109–171, §5114(a)(1), substituted “and services described in subsections (qq) and (vv)” for “and”, in subpart (A) and “section 339” for “sections 329, 330, and 340” in subpart (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, §803(a)(2), inserted “or would have been so included but for the application of section 1395w–3b of this title)” after “in the physicians’ bills”.

Subsec. (v)(1)(T)(ii). Pub. L. 106–554, §1(a)(6) [title V, §541(h)], substituted “during a fiscal year 2000” for “during a subsequent fiscal year” and “,” and for period at end.


Subsec. (ff)(3)(B). Pub. L. 106–554, §1(a)(6) [title V, §431(a)], substituted “entity—that—” for “entity—,” added cl. (i) to (iii), and struck out former clss. (i) and (ii) which read as follows:

“(i) providing the services described in section 1916(c)(4) of the Public Health Service Act; and

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

Subsec. (nn)(1), (2). Pub. L. 106–554, §1(a)(6) [title I, §101(a)], substituted “3 years” for “2 years”.

Subsec. (pp)(2). Pub. L. 106–554, §1(a)(6) [title I, §103(a)(2)], substituted “provides the Secretary on a continuing basis with a surety bond in a combined amount that is not less than $50,000; and”.


Subsec. (oo)(7). Pub. L. 106–113, §1000(a)(6) [title III, §304(a)], amended par. (7) generally. Prior to amendment, par. (7) read as follows: “provides the Secretary on a continuing basis with a surety bond in a combined amount that is not less than $50,000; and”.

Subsec. (pp)(1). Pub. L. 106–113, §1000(a)(6) [title II, §221(b)(1)(A)], substituted “(i), (iii), or (iv)” for “(i)” and “(3), or (4)” for “(3)”.

Subsec. (rr)(4). Pub. L. 106–113, §1000(a)(6) [title II, §221(b)(1)(B)], inserted before semicolon at end “plus such additional number of months (if any) provided under section 1385(k) of this title”.


Subsec. (vv)(1)(S)(ii)(I), (II). Pub. L. 106–113, §1000(a)(6) [title II, §201(k)], substituted “and until the date that the prospective payment system under section 1395x of this title is implemented” for “and during fiscal year 2000 before January 1, 2000”.


Subsec. (ss)(1)(G)(i). Pub. L. 106–113, §1000(a)(6) [title VI, §321(k)(9)(B)], which directed substitution of “or” for “of”, was executed by making the substitution for “of” the second time appearing to reflect the probable intent of Congress.

Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(9)(A)], substituted “owned” for “owned”.


other provider charges or is paid any amounts with respect to the furnishing of such services.

Subsec. (s)(2)(K)(ii). Pub. L. 105–33, § 4511(a)(1), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: "services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(6) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) in a rural area (as defined in section 1395ww(e)(2)(D) of this title) which the nurse practitioner is legally authorized to perform by the State in which the services are performed.

Subsec. (s)(2)(K)(iii). Pub. L. 105–33, § 4601(a), struck out closing provisions which read as follows: "of the mean of the labor-related and nonlabor for free standing home health agencies.


Subsec. (v)(1)(L)(iii). Pub. L. 105–33, § 4604(b), substituted "service is furnished" for "agency is located.


Subsec. (v)(1)(L)(v) to (vii). Pub. L. 105–33, § 4602(c), added cls. (v) to (vii).

Subsec. (v)(1)(O)(i). Pub. L. 105–33, § 4404(a)(1), struck out "and (if applicable) a return on equity capital after "capital indebtedness" and substituted "provider of services" for "hospital or skilled nursing facility", "clause (iii)" for "clause (iv)", and "the historical cost of the asset, as recognized under this subchapter, less depreciation allowed, to the owner of record as of August 5, 1997 (or, in the case of an asset not in existence as of August 5, 1997, the first owner of record of the asset after August 5, 1997)" for "the lesser of the allowable acquisition cost of such asset to the owner of record as of July 18, 1984 (or, in the case of an asset not in existence as of such date, the first owner of record of the asset after such date), or the acquisition cost of such asset to the new owner.

Subsec. (v)(1)(O)(ii) to (iv). Pub. L. 105–33, § 4404(a)(2), (3), redesignated cls. (iii) and (iv) as (ii) and (iii), respectively, and struck out former cl. (ii) which read as follows: "Such regulations shall provide for recapture of depreciation in the same manner as provided under the regulations in effect on June 1, 1994;"


Subsec. (y)(1). Pub. L. 105–33, § 4454(a)(1)(B)(ii), inserted "includes a Christian Science sanatorium operated, or licensed 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."

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 freestanding home health agencies before comma at end and realigned margins.

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.


Pub. L. 101–508, §4151(b)(1)(B), substituted “subclauses (I) and (II)” for “subclause (I)” and “the costs reflected” for “capital-related costs reflected.”


Pub. L. 101–508, §4161(b)(1), inserted at end “If a State agency has determined under section 1395x(a)(10) of this title that a facility is a rural health clinic and the facility has applied to the Secretary for certification as such a clinic, the Secretary shall notify the facility of the the Secretary’s approval or disapproval of the certification not later than 60 days after the date of the State agency determination or the application (whichever is later).”


Pub. L. 101–508, §4161(a)(2)(B), which directed amendment of par. (3) by substituting “the previous provisions of this subsection” for “paragraphs (1) and (2)” could not be executed because the words “paragraphs (1) and (2)” did not appear after amendment by Pub. L. 101–508, §4155(d). See below.

Pub. L. 101–508, §4155(d), substituted “‘The term ‘physician assistant’, the term ‘nurse practitioner’, and the term ‘clinical diagnostic laboratory test’” for “‘screening mammography’” for “‘covered osteoporosis drug’”).


Subsec. (ff)(3). Pub. L. 101–508, §4162(a), designated existing provision as subpar. (A), substituted “‘outpatients or by a community mental health center (as defined in subparagraph (B))’” for “‘outpatients’”, and added subpar. (B).


Subsec. (a). Pub. L. 101–124, §104(d)(4)(A), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (e). Pub. L. 101–239, §6101(a)(1), inserted at end “The term ‘hospital’ does not include, unless the context otherwise requires, a rural primary care hospital (as defined in subsection (m)(1) of this section).”

Pub. L. 101–234, §101(a), inserted Pub. L. 100–360, §104(d)(4)(B), 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. (i). Pub. L. 101–234, §201(a), inserted Pub. L. 100–360, §104(d)(4)(C), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (m). Pub. L. 101–234, §201(a), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

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

Subsec. (q). Pub. L. 101–239, §6114(a)(1), substituted “‘a hospital 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 laboratory tests exceeding 5,000 per year,” in provisions following par. (14).


Pub. L. 101–234, §201(a), inserted Pub. L. 100–360, §202(a)(1), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (s)(2)(K). Pub. L. 101–239, §6114(a)(2), added cl. (ii), redesignated former cl. (ii) as (iii), and substituted “‘to services described in clause (i) or (ii)” for “‘to such services”’ in cl. (iii).


Subsec. (s)(13). Pub. L. 101–234, §201(a), which repealed Pub. L. 100–360, §204(a)(1)(B)–(D), and directed that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, was executed by striking out par. (13) as added by Pub. L. 100–360, §204(a)(1)(B)–(D), but former par. (13) which was redesignated (14) was not restored in view of intervening redesignation as (15) by Pub. L. 101–239, §6115(a)(1)(C), see 1988 Amendment note below.


Pub. L. 101–234, §201(a), which repealed Pub. L. 100–360, §204(a)(1)(A), and directed that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, was not executed in view of intervening redesignation of par. (14) as (15) by Pub. L. 101–239, §6115(a)(1)(C), see 1988 Amendment note below.


Pub. L. 101–234, §201(a), which repealed Pub. L. 100–360, §204(a)(1)(A), and directed that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, was not executed in view of intervening redesignation of par. (15) as (16) by Pub. L. 101–239, §6115(a)(1)(C), see 1988 Amendment note below.

Subsec. (s)(16). Pub. L. 101–239, §6114(a)(2), (3), added subpar. (A) and designated existing provisions as subpar. (B).


Subsec. (t). Pub. L. 101–234, §201(a), repealed Pub. L. 100–360, §202(a)(2), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.


Pub. L. 101–234, §201(a), repealed Pub. L. 100–360, §204(e)(1), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (v)(1)(G)(i). Pub. L. 101–234, §101(a), amended Pub. L. 100–360, §104(d)(4)(D), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

visions 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. (a)(1). Pub. L. 100–360, §104(d)(4)(C), struck out "hospital or rural primary care hospital" after "hospital.

Subsec. (w)(2). Pub. L. 101–239, §6213(b), substituted "hospital or rural primary care hospital" for "hospital" in six places.

Subsec. (y). Pub. L. 101–234, §101(a), repealed Pub. L. 100–360, §104(d)(4)(E), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (aa)(3). Pub. L. 101–239, §6213(b), substituted "as defined in paragraph (3)," by "as defined in paragraph (3), or by" and inserted "or by a clinical social worker (as defined in subsection (hh)(1) of this section)," after "Secretary.


Subsec. (hh). Pub. L. 101–239, §6113(b)(2)(B), inserted "clinical social worker services" after "social work-
er" in heading, redesignated existing provisions as par. (1), redesignated former pars. (1) to (3) as subs. (A) to (C), respectively, in subpar. (C), redesignated former subpars. (A) to (B) as cls. (i) and (ii), respectively, in cl. (ii), redesignated former cls. (i) and (ii) as subcl. (i) and (ii), respectively, and added subj. (C). Pub. L. 101–239, §6113(a), added subpar. (J) and redesignated former subpar. (J) as (K).


Subsec. (ii). Pub. L. 101–239, §6113(a), struck out "on site at a community mental health center (as such term is used in the Public Health Service Act), and such services that are necessarily furnished off-site (other than at an off-site office of such psychologist) as part of a treatment plan because of the inability of the individual furnished such services to travel to the center by reason of physical or mental impairment, because of institutionalization, or because of similar circumstances of the individual," after "as defined by the Secretary.

Subsecs. (j) to (l). Pub. L. 101–234, §201(a), repealed Pub. L. 100–360, §§203(b), 204(a)(2), 205(b), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 Amendment notes below.


1988—Subsec. (a). Pub. L. 100–360, §104(d)(4)(A), struck out subsec. (a) which defined "spell of illness".


Subsec. (c)(1). Pub. L. 100–360, §104(d)(4)(B), substituted "and paragraph (7) of this subsection" for "paragraph (7) of this subsection and paragraph (5) of this subsection.

Subsec. (e). Pub. L. 100–360, §104(d)(4)(B), substituted "and paragraph (7) of this subsection for "paragraph (7) of this subsection and paragraph (5) of this subsection.

Subsec. (i). Pub. L. 100–360, §104(d)(4)(C), struck out subsec. (i) which defined "post-hospital extended care services".

Subsec. (m). Pub. L. 100–360, §206(a), inserted at end "For purposes of paragraphs (1) and (4) and sections 1395f(a)(2)(C) and 1395n(a)(2)(A) of this title, nursing care and home health aide services shall be considered to be provided or needed on an 'intermittent' basis if they are provided or needed less than 7 days each week and, in the case they are provided or needed for a period of up to 38 consecutive days.


Subsec. (o). Pub. L. 100–360, §411(l)(1)(B), inserted "except that such term does not include such equipment fur-
nished 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. 100–667, §424(a), inserted at end "Nothing in this subsection shall be construed as re-
quiring, with respect to outpatients who are not enti-
tled to benefits under this subchapter, a physical thera-
pist to provide outpatient physical therapy services only to outpatients who are under the care of a physi-
cian or pursuant to a plan of care established by a physi-
cian.

Subsec. (s). Pub. L. 100–360, §411(b)(3)(B), inserted a comma before "year" in provisions immediately pre-
ceding par. (13).


Subsec. (s)(4). Pub. L. 100–360, §204(a)(1)(B)–(D), added par. (13) relating to screening mammography (as defined in subsection (kk) of this section). Former par. (13) redesignated (14).


the institution is accredited by the Joint Commission on Accreditation of Hospitals or if such distinct part meets requirements equivalent to such accreditation requirements as determined by the Secretary in concluding provisions.

Subsec. (g). Pub. L. 98–369, §2335(b)(1), struck out subsec. (g) which defined "tuberculosis hospital.

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

Subsec. (j)(2). Pub. L. 98–433, §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. (a)(2)(b). Pub. L. 98–21, §602(a)(1), which directed the substitution of "and durable medical equipment" for ", and the use of medical appliances" was executed by making the substitution for ", and the use of medical appliances" as the probable intent of Congress.

Subsec. (n). Pub. L. 98–369, §2321(e)(3), added subsec. (n). Subsec. (p)(1). Pub. L. 98–369, §2341(a), substituted "paragraph (1) or (3) of subsection (r) of this section" for "paragraph (r)(1) of this section".

Subsec. (p)(2). Pub. L. 98–21, §621(e)(1), which directed the substitution of "a physician as so defined" or by a qualified physical therapist and is periodically reviewed by a physician (as so defined) for ", and is periodically reviewed, by a physician (as so defined)"

Subsec. (r)(3). Pub. L. 98–617, §3(b)(7), substituted "under subsections (k), (m), and (p)(1) of this section and sections 1395f(a), 1395a(2)(F)(i)(1), and 1395n of this title for "under subsections (k) and (m) and sections 1395f(a) and 1395n of this title before "is consistent with the policy".

Pub. L. 98–369, §2314(c), substituted "for the purposes of subsections (k), (m), and (p)(1) of this section" for "for the purposes of subsections (k) and (m) of this section", and substituted "sections 1395f(a), 1395a(2)(F)(i)(1), and 1395n of this title" for "sections 1395f(a) and 1395n of this title but only if" for "sections 1395f(a) and 1395n of this title but only if".


Subsec. (s)(6). Pub. L. 98–369, §2321(e)(2), struck out provision which included iron lungs, oxygen tents, etc., with durable medical equipment. See subsec. (n) of this section.

Subsec. (s)(10). Pub. L. 98–369, §2323(a), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (s)(11). Pub. L. 98–369, §2341(b)(20), struck out "or" before "home health agency".


Subsec. (v)(1)(C)(i). Pub. L. 98–369, §2354(b)(22), inserted a dash after ", but only if".


Pub. L. 98–369, §2354(b)(21)(C), inserted a comma after "section 1395k(a)(2)(B)(i) of this title".

Subsec. (v)(1)(E). Pub. L. 98–369, §2319(a)(1), struck out cl. (i) which directed that such regulations provide that any determination of reasonable cost with respect to services provided by hospital-based skilled nursing facilities be made on the basis of a single standard based on the reasonableness of costs incurred by free standing skilled nursing facilities, subject to such adjustments as deemed appropriate by the Secretary, and struck out the designation ("ii")


Subsec. (v)(1)(I)(i), (ii). Pub. L. 98–369, §2354(b)(24), substituted "by the Secretary, or upon request by the Comptroller General" for "to the Secretary, or upon request to the Comptroller General".

Subsec. (v)(1)(K). Pub. L. 98–369, §2318(a), (b), designated existing provisions as cl. (i), substituted there-
any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities for provisions that such regulations would provide that an inpatient routine nursing salary cost differential would be allowable as a reimbursable cost of hospitals, at a rate not to exceed 5 percent, to be applied under the same methodology used for the nursing salary cost differential for the month of April

Subsec. (v)(1)(L). Pub. L. 97–248, §101(a)(2), struck out cl. (i) which provided that the Secretary, in determining the amount of the payments that could be made under this subchapter with respect to routine operating costs for the provision of general inpatient hospital services, could not recognize as reasonable, routine operating costs for the provision of general inpatient hospital services by a hospital to the extent these costs exceeded 108 percent of the mean of such routine operating costs per diem for hospitals, or, in the judgment of the Secretary, such lower percentage or such comparable or lower limit as the Secretary could determine, and struck out “(“i“)”. Pub. L. 97–248, §105(a), inserted “free standing” after “costs per visit for”. Subsec. (v)(1)(M). Pub. L. 97–248, §106(a), added subpar. (M).


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


1981—Subsec. (u). Pub. L. 97–35, §221(c), struck out “detoxification facility,” after “home health agency,”. Subsec. (v)(1)(G)(I). Pub. L. 97–35, §2102(a)(1), substituted “there is not an excess of hospital beds in such hospital and (subject to clause (iv)) there is not an excess of hospital beds in the area of such hospital” for “the hospital had (during the immediately preceding calendar year) an average daily occupancy rate of 80 percent or more” in provision following subcl. (III).

Pub. L. 97–35, §2114, substituted “the Secretary or such agent as the Secretary may designate” for “an organization or agency with review responsibility as is otherwise provided for under part A of subchapter XI of this chapter” in provision preceding subcl. (I).

Subsec. (v)(1)(G)(IV). Pub. L. 97–35, §2102(a)(2), substituted provisions that the determination under cl. (i) of this subparagraph, in the case of a public hospital, whether or not there is an excess of hospital beds in the area of such hospital, be made on the basis of only the public hospitals which are in the area of the hospital and which are under common ownership with that hospital for provisions that public hospitals under common ownership may be treated as a single hospital, and beginning two years after the date this subparagraph is first applied with respect to a hospital, the Secretary, to the extent feasible, shall not treat as an inpatient an individual with respect to whom payment was made to the hospital only because of this subparagraph or section 1396a(h) of this title for such determination.


Subsec. (2). Pub. L. 96–499, § 933(d), which purported to substitute “skilled nursing facility, comprehensive outpatient rehabilitation facility,” for “extended care facility,” was executed by inserting “comprehensive outpatient rehabilitation facility,” after “skilled nursing facility,” as the probable intent of Congress, in view of the substitution as noted above of the phrase “skilled nursing facility” for “extended care facility” by section 278(b)(6) of Pub. L. 92–603.

Subsec. (aa)(1)(A). Pub. L. 96–499, § 933(d), inserted reference to items and services described in subsection (a)(10) of this section.


1977—Subsec. (j)(11). Pub. L. 95–142, § 3(a)(2), substituted provisions relating to compliance with requirements of section 1220a–3 of this title, for provisions relating disclosure of ownership, corporate status, etc., information to the Secretary or his delegate.

Subsec. (j)(13). Pub. L. 95–142, § 21(a), struck out “and” after “nursing facilities”.


Subsec. (s). Pub. L. 95–210, § 1(g), (h), added subpar. (E) of par. (2) and in provisions following par. (9) inserted a rural health clinic,” after “independent of a physician’s office”.

Subsec. (s)(6). Pub. L. 95–216 inserted “(which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual’s medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe)” after “wheelchairs”.


Subsec. (w)(2). Pub. L. 95–142, § 5(m), inserted “part B of this subchapter or under” after “or entitled to have payment made for such services under”.


Subsec. (w). Pub. L. 94–182, § 112(a)(1), designated existing provisions as par. (1) and in subsection as redesignated former par. (10) as (11), added par. (2).


Subsec. (b)(b)(6). Pub. L. 92–603, §§ 227(a), 278(a), redesignated existing second sentence of subsec. (b) as par. (6) and in subsec. (b)(6) as so designated inserted reference to services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of podiatry, approved by the Council on Podiatry Education of the American Podiatry Association.


Subsec. (e). Pub. L. 92–603, § 211(b), inserted reference to section 1395f(f) of this title in the provisions preceding par. (1), inserted reference to sections 1395f(f)(2) of this title after “For purposes of sections 1395f(d) and 1395f(b) of this title (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections),” and inserted provisions for accreditation by the Joint Commission on Accreditation of Hospitals.


Subsec. (e)(9). Pub. L. 92–603, §§ 234(a), 244(c), redesignated former par. (9) as (9) and struck out provisions requiring that other requirements not be higher than the comparable requirements prescribed for the accreditation of hospitals by the Joint Commission on Accreditation of Hospitals.

Subsec. (f)(2), (g)(2). Pub. L. 92–603, § 234(b), (c), inserted reference to par. (9) of subsection (f), redesignated former par. (9) as (10) as redesignated by Pub. L. 95–210, § 1(d), added subsec. (bb).

Subsec. (h). Pub. L. 92–603, § 278(a)(5), substituted “skilled nursing facility” for “extended care facility”, “skilled nursing facilities” for “extended care facilities” and “a” for “an”.

Subsec. (i). Pub. L. 92–603, §§ 248, 278(a)(6), (b)(10), extended the class of persons qualifying to be deemed as having been an inpatient in a hospital immediately before the date of enactment of this title as redesignating as physicians legally authorized to practice such art in the country in which inpatient hospital services referred to in section
1395y(a)(4) are furnished, added cl. (4) covering doctors of optometry who are legally authorized to practice optometry by the State in which they perform such functions, but only with respect to establishing the necessity for prosthetic lenses, and added cl. (5) providing for the inclusion of chiropractic services.

Subsec. (s)(8). 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(m) 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), 248(b), 278(b)(11), inserted definition of the costs of services, inserted provision that the regulation for the establishment of limits on the direct or indirect overall incurred costs or incurred costs of specific items or services or groups of items or services to be recognized as 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 deliverable 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). (C) and substituted “skilled nursing facilities” for “extended care facilities”.

Subsec. (v)(3). Pub. L. 92–603, § 278(a)(13), substituted “skilled nursing facility” for “inpatient hospital”.


Subsec. (v)(6). Pub. L. 92–603, §§ 223(f), 251(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. (z). Pub. L. 92–603, §§ 234(b), 278(b)(6), added subpar. (1) which substituted “skilled nursing facility” for “extended care facility”.

1971—Subsec. (e)(5). Pub. L. 91–690 authorized the Secretary, until January 1, 1976, to waive the requirement relating to the provision of 24 hour nursing service rendered or supervised by a registered professional nurse.

1968—Subsec. (e). Pub. L. 90–248, § 129(c)(9)(C), inserted reference to section 1396a(a)(3) in first and third sentences and substituted “or diagnostic services” after “hospital services” in third sentence.

Pub. L. 90–248, § 144(a), in second sentence after par. (6), 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 service, be licensed as a hospital, and be primarily engaged in providing not nursing care and related services but medical or rehabilitative care by or under the supervision of a doctor of medicine or osteopathy.

Subsec. (p). Pub. L. 90–248, §§ 129(c)(10), 133(b), struck out definition of “outpatient hospital diagnostic services” and inserted definition of “outpatient physical therapy services”, respectively.


Subsec. (r). Pub. L. 90–248, § 144(a)–(c), struck out “unless they would otherwise constitute inpatient hospital services, extended care services, or home health services” after “items or services” in said preceding par. (1), inserted after “hospital” in sentence following par. (9) “which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395d(b) of this title”, and inserted sentence following par. (13) providing that medical and other health services (other than physicians’ services and services incident to physicians’ services) furnished a patient of a facility which meets the definition of a hospital for emergency services will be covered under the medical insurance program only if such facility satisfies such health and safety requirements as are appropriate for the item or service furnished as the Secretary may determine.

Subsec. (s)(2)(A) to (C). Pub. L. 90–248, § 128(a), designated existing provisions as subpars. (A) and (B) and added subpar. (C).


Subsec. (s)(3). Pub. L. 90–248, § 134(a), included in medical and other health services diagnostic X-ray tests furnished in the patient’s home under the supervision of a physician if the tests meet such health and safety conditions as the Secretary finds necessary.

Subsec. (s)(6). Pub. L. 90–248, § 132(a), provided that payments may be made with respect to expenses incurred in the purchase as well as in the rental of durable medical equipment.

Pub. L. 90–248, § 144(d), inserted “other than in institution that meets the requirements of subsection (e)(1) or (j)(1) of this section”.

Subsec. (s)(12), (13). Pub. L. 90–248, § 129(b), added paras. (12) and (13) which excluded from the diagnostic services or services (other than physician’s services) certain items or services.

Pub. L. 90–248, § 129(c)(11), substituted “1396a(a)(3)” for “1395e(a)(4)”.

1966—Subsec. (v)(1). Pub. L. 89–713 inserted provisions which required that, in the case of extended care services furnished by proprietary facilities, the regulations include provision for specific recognition of a reasonable and allowable return on equity capital and which placed a limitation on the rate of return of one and one-half times the average of the rates of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 109–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT


Amendment by section 4103(a), (b) of Pub. L. 111–148 applicable to items and services furnished on or after Jan. 1, 2011, see section 4103(e) of Pub. L. 111–148, set out as a note under section 1395f of this title.

Amendment by section 4104(a) of Pub. L. 111–148 applicable to items and services furnished on or after Jan. 1, 2011, see section 4104(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.


EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–316, § 7(b), Oct. 8, 2008, 122 Stat. 3895, provided that: “The amendments 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 4102(a), (c), of Pub. L. 103–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4102(e) of Pub. L. 103–33, set out as a note under section 1395f of this title.

Amendment by section 4103(a) of Pub. L. 103–33 applicable to items and services furnished on or after Jan. 1, 2000, see section 4103(e) of Pub. L. 103–33, set out as a note under section 1395f of this title.

Amendment by section 4104(a)(1) of Pub. L. 103–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 103–33, set out as a note under section 1395f of this title.

Amendment by section 4105(a)(1), (b)(1) of Pub. L. 103–33 applicable to items and services furnished on or after July 1, 1998, see section 4105(d)(1) of Pub. L. 103–33, set out as a note under section 1395f of this title.

Section 4106(d) of Pub. L. 103–33 provided that: "The amendments made by this section [amending this section and section 1395u of this title] take effect as of the date of enactment of this Act [Aug. 5, 1997]."

Amendment by section 4201(c)(1), (2) of Pub. L. 103–33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 103–33, set out as a note under section 1395f of this title.

Section 4205(d)(4) of Pub. L. 105–33 provided that: "The amendment made by subsection (a) [amending this section] applies to items and services furnished on or after January 1, 1998."
section] shall apply with respect to cost reporting periods beginning on or after July 1, 1996.’’

**Effective Date of 1993 Amendment**

Section 13503(c)(2) of Pub. L. 101–66 provided that:

‘‘The amendments made by paragraph (1) [amending this section and section 1395oo of this title] shall take effect on October 1, 1993.’’

Section 13553(c) of Pub. L. 101–66 provided that: ‘‘The amendments made by subsections (a) and (b) [amending this section] shall apply to items furnished on or after January 1, 1994.’’

Section 13554(b) of Pub. L. 101–66 provided that: ‘‘The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1994.’’

Section 13556(b) of Pub. L. 101–66 provided that: ‘‘The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 4161(a)(2)(C) of ORSHA-1990 [Pub. L. 101–508].’’

Section 13564(b)(2) of Pub. L. 101–66 provided that: ‘‘The amendments made by this section [amending this section and section 1395rr of this title] shall apply to items and services furnished on or after January 1, 1994.’’

**Effective Date of 1990 Amendment**


Amendment by section 4152(a)(2) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1991, see section 4152(a)(3) of Pub. L. 101–508, set out as a note under section 1395m of this title.

Amendment by section 4153(b)(2)(C) of Pub. L. 101–508 provided that: ‘‘The amendments made by subparagraphs (A) and (B) [amending this section and section 1395yr of this title] shall apply to items furnished on or after January 1, 1991.’’

Amendment by section 4155(a), (d) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4155(e) of Pub. L. 101–508, set out as a note under section 1395s of this title.

Amendment by section 4157 of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4157(d) of Pub. L. 101–508, set out as a note under section 1395s of this title.

Amendment by section 4161(a)(1), (2), (3) 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 1395t of this title.

Amendment by section 4161(b)(5) of Pub. L. 101–508 provided that:

‘‘This subsection [amending this section and section 1395oo of this title and enacting provisions set out as a note below] shall take effect on October 1, 1991, except that the amendment made by paragraph (4) [amending section 1395oo of this title] shall apply to cost reports for periods beginning on or after October 1, 1991.’’

Amendment by section 4162(a) of Pub. L. 101–508 applicable with respect to partial hospitalization services provided on or after Oct. 1, 1991, see section 4162(c) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4163(a) of Pub. L. 101–508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e) of Pub. L. 101–508, set out as a note under section 1395l of this title.

Amendment by section 4201(d)(4) of Pub. L. 101–508 provided that:

‘‘The amendments made by paragraphs (1) and (2) [amending this section and section 1395rr of this title] shall apply to items and services furnished on or after July 1, 1991.’’


**Effective Date of 1989 Amendments**

Amendment by section 6112(e)(1) of Pub. L. 101–239 applicable with respect to items furnished on or after Jan. 1, 1990, see section 6112(e)(4) of Pub. L. 101–239, set out as a note under section 1395m of this title.

Amendment by section 6113(a)–(b)(2) of Pub. L. 101–239 applicable to services furnished on or after July 1, 1990, see section 6113(e) of Pub. L. 101–239, set out as a note under section 1395f of this title.

Amendment by section 6114(a), (d) of Pub. L. 101–239 applicable to services furnished on or after Apr. 1, 1990, see section 6114(f) of Pub. L. 101–239, set out as a note under section 1396a of this title.

Amendment by section 6115(b) of Pub. L. 101–239 provided that: ‘‘The amendments made by this section [amending this section and sections 1395y, 1395aa, 1395bb, 1396a, and 1396n of this title] shall apply to therapeutic shoes and inserts furnished on or after July 1, 1989, and additional provisions providing for applicable with respect to the reorganization of the National Health Insurance Program provided after July 1, 1989, set out as a note under section 1395f of this title.

Amendment by section 6114(b) of Pub. L. 101–239 provided that: ‘‘The amendments made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].’’


Amendment by section 201(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1322a–7a of this title.

**Effective Date of 1988 Amendment**

Section 8423(b) of Pub. L. 100–647 provided that: ‘‘The amendments made by subsection (a) [amending this section] shall be effective with respect to services furnished on or after January 1, 1989.’’

Section 8423(b) of Pub. L. 100–647 provided that: ‘‘The amendments made by subsection (a) [amending this section] shall become effective with respect to services provided after December 31, 1988.’’

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 104(d)(4) of Pub. L. 100–360 effective Jan. 1, 1989, except as otherwise provided, and applicable to inpatient hospital deductible for 1989 and succeeding years, to care and services furnished on or after Jan. 1, 1989, to premiums for January 1989 and succeeding months, and to blood or blood cells furnished on or after Jan. 1, 1989, see section 104(a) of Pub. L. 100–360, set out as a note under section 1395d of this title.

Amendment by section 202(a) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(a)(1) of Pub. L. 100–360, set out as a note under section 1396a of this title.

Amendment by section 203(b), (e)(1) of Pub. L. 100–360 applicable to items and services furnished on or after July 1, 1991, see section 203(b) of Pub. L. 100–360, set out as a note under section 1396a of this title.
Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Amendment by section 204(a) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 205(b) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(f) of Pub. L. 100–360, set out as a note under section 1395k of this title.

Section 206(b) of Pub. L. 100–360, which provided that the amendment of this section by section 206(a) of Pub. L. 100–360 applied to services furnished in cases of initial periods of home health services beginning on or after January 1, 1990, was repealed by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1361.

As excepted as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(d)(5)(A), (g)(3)(H), (h)(1)(B)–(D)(3)(A), (4)(D), (5)–(7)(A), (E), (F), (1)(D), (4)(C)(iii), (h)(1)(B), (C) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title I, General Provisions.

411(d)(1)(B)(ii) of Pub. L. 100–360 provided that: "The amendment made by clause (i) [amending this section] shall apply to equipment furnished on or after the effective date provided in section 402(c) of OBRA [Pub. L. 100–203, set out below]."

**EFFECTIVE DATE OF 1987 AMENDMENT**

Section 4009(e)(2) of Pub. L. 100–203 provided that: "The amendment made by paragraph (1) [amending this section] shall apply with respect to services furnished on or after April 1, 1988."

Section 4021(c) of Pub. L. 100–203 provided that: "Except as otherwise provided, the amendments made by subsections (a) and (b) [enacting section 1395bbb of this title and amending this section] shall apply to home health agencies as of the first day of the 18th calendar month that begins after the date of the enactment of this Act [Dec. 22, 1987]."

Section 4028(a)(2) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 411(d)(b)(B), July 1, 1988, 102 Stat. 775, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after July 1, 1989.

Section 4064(e)(2) of Pub. L. 100–203 provided that: "The amendments made by this section shall become effective on the date of enactment of this Act [Dec. 22, 1987]."

Section 4072(a)(c) of Pub. L. 100–203 provided that: "(A) The amendments made by subsection (b) [amending this section and sections 1395j and 1395m of this title] shall become effective on the date of enactment of this Act [Dec. 22, 1987]."

"(B) The Secretary of Health and Human Services shall implement the amendments made by subsection (b) so as to ensure that there is no additional cost to the medicare program by reason of such amendments."


"(2) In conducting the demonstration project pursuant to paragraph (1), in order to determine the cost effectiveness of including influenza vaccine in the medicare program, the Secretary of Health and Human Services is required to conduct a demonstration of the provision of influenza vaccine as a service for medicare beneficiaries and to expend $25,000,000 each year of the demonstration project for this purpose. In conducting the demonstration, the Secretary is authorized to pur chase in bulk influenza vaccine and to distribute it in a manner to make it widely available to medicare beneficiaries, to develop projects to provide vaccine in the same manner as other demonstration projects, and to engage in other appropriate use of moneys to provide influenza vaccine to medicare beneficiaries and evaluate the cost-effectiveness of such projects. In determining cost-effectiveness, the Secretary shall consider the direct cost of the vaccine, the utilization of vaccine which might otherwise not have occurred, the costs of illnesses and nursing home days avoided, and other relevant factors, except that extended life for beneficiaries shall not be considered to reduce the cost effectiveness of the vaccine.''

Section 4075(b) of Pub. L. 100–203 provided that: "(1) The amendments made by this section [amending this section and sections 1395j, 1395l, 1395ma, 1395bb, 1395c, 1395dd, and 1395n of this title] shall become effective (if at all) in accordance with paragraph (2).

"(2)(A) The Secretary of Health and Human Services (in this paragraph referred to as the ‘Secretary’), shall establish a demonstration project to begin on October 1, 1988, to test the cost-effectiveness of furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section to a sample group of medicare beneficiaries.

"(B)(i) The demonstration project under subparagraph (A) shall be conducted for an initial period of 24 months. Not later than October 1, 1988, the Secretary shall report to the Congress on the results of such project. If the Secretary finds, on the basis of existing data, that furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section is cost-effective, the Secretary shall include such finding in such report, such project shall be discontinued, and the amendments made by this section shall become effective on November 1, 1990.

"(ii) If the Secretary determines that such finding cannot be made on the basis of existing data, such project shall continue for an additional 24 months. Not later than October 1, 1990, the Secretary shall report to the Congress on the results of such project. The amendments made by this section shall become effective on the first day of the first month following the date after which such report is submitted to the Congress unless the report contains a finding by the Secretary that furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section is not cost-effective (in which case the amendments made by this section shall not become effective).


Amendment by section 4073(a), (c) of Pub. L. 100–203 effective with respect to services performed on or after January 1, 1988, see section 4073(e) of Pub. L. 100–203, set out as a note under section 1395k of this title.

Section 4075(b) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section] shall be effective with respect to services performed on or after January 1, 1988."

Section 4072(c) of Pub. L. 100–203 provided that: "The amendment made by subsection (a) [amending this section] shall apply to drugs dispensed on or after the date of the enactment of this Act [Dec. 22, 1987]."

Section 4073(b) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section] shall apply with respect to services furnished on or after January 1, 1988."
ished on or after the date of enactment of this Act [Dec. 22, 1987]."

Amendment by section 4977(b)(1), (4) of Pub. L. 100–203 effective with respect to services performed on or after July 1, 1988, see section 4977(b)(5) of Pub. L. 100–203, as amended, set out as a note under section 1395k of this title.

Amendment by section 4984(c)(1) of Pub. L. 100–203 applicable to services furnished after Dec. 31, 1988, see section 4984(c)(3) of Pub. L. 100–203, as added, set out as a note under section 1395k of this title.

Amendments by section 4201(a)(1), (b)(1), (d)(1), (2), (5) of Pub. L. 100–203 applicable to services furnished on or after Oct. 1, 1990, without regard to whether regulations to implement such amendments are promulgated by such date, except as otherwise specifically provided in section 1395i–3 of this title, see section 4204(a) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1395i–3 of this title.

**Effective Date of 1986 Amendments**

Section 9305(c)(4) of Pub. L. 99–509 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]."

Section 9313(a)(3) of Pub. L. 99–509 provided that: "The amendments made by this paragraph [probably mistaken] which amended this section and section 1395ff of this title] take effect on the date of the enactment of this Act [Oct. 21, 1986]."

Section 9323(a)(1), (c), (f) of Pub. L. 99–509 applicable to services furnished on or after Jan. 1, 1989, with exceptions for hospitals located in rural areas which meet certain requirements related to certified registered nurse anesthetists, see section 9323(f)(1), (k) of Pub. L. 99–509, as amended, set out as notes under section 1395k of this title.

Section 9350(c)(2) of Pub. L. 99–509 provided that: "The amendments made by paragraph (1) [amending this section] shall apply to immunosuppressive drugs furnished on or after January 1, 1987.

Section 9378(b) of Pub. L. 99–509 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1987.

Section 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.

Section 9338(f) of Pub. L. 99–509 provided that: "The amendments made by this subsection [amending this section] shall apply to services furnished on or after January 1, 1987.

Section 9107(c)(2) of Pub. L. 99–272 provided that: "The amendments made by subsection (b) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1985."

Section 9110(b) of Pub. L. 99–272 provided that: "The amendments made by subsection (a) [amending this section] shall be applied as though they were originally included in the Deficit Reduction Act of 1984 [Pub. L. 98–369]."

Section 9201(c)(2) of Pub. L. 99–272 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after July 1, 1986."


Section 9219(b)(3)(B) of Pub. L. 99–272 provided that: "The amendment made by subparagraph (A) [amending this section] shall be effective as if it had been originally included in the Social Security Amendments of 1983 [Pub. L. 98–21]."

**Effective Date of 1984 Amendments**

Amendment by Pub. L. 98–617 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L. 98–369, see section 3(c) of Pub. L. 98–617, set out as a note under section 1395f of this title.

Section 2314(c)(1), (2) of Pub. L. 98–369 provided that: "(1) Clause (i) of section 1861(v)(1)(O) of the Social Security Act [subsec. (v)(1)(O)(i) of this section] 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 (ii) of section 1861(v)(1)(O) of such Act [subsec. (v)(1)(O)(ii) of this section] shall apply to costs incurred on or after the date of the enactment of this Act."

Section 2318(c) of Pub. L. 98–369 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 1395f 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 1395t of this title.

Section 2322(b) of Pub. L. 98–369 provided that: "The amendments made by subsection (a) [amending this section] shall be effective with respect to services furnished on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2323(a) of Pub. L. 98–369 applicable to services furnished on or after Sept. 1, 1984, see section 2323(d) of Pub. L. 98–369, set out as a note under section 1395 of this title.

Section 2323(b) of Pub. L. 98–369 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 2323(b) of Pub. L. 98–369 effective July 18, 1984, see section 2323(g) of Pub. L. 98–369, set out as a note under section 1395 of this title.

Section 2324(c) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section and section 1396d of this title] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2341(a), (c) of Pub. L. 98–369 applicable to services furnished on or after July 18, 1984, see section 2341(d) of Pub. L. 98–369, set out as a note under section 1395k of this title.

Amendment by section 2342(a) of Pub. L. 98–369 applicable to plans of care established on or after July 18, 1984, see section 2342(c) of Pub. L. 98–369, set out as a note under section 1395n of this title.

Section 2343(c) of Pub. L. 98–369 provided that: "The amendments made by subsection (a) and (b) [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2351(b) 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 2351(e)(1) of Pub. L. 98–369, set out as a note under section 1395ww of this title.

**Effective Date of 1983 Amendments**

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, Pub. L. 97–248, to which such
amendment relates, see section 309(c)(1) of Pub. L. 97–488, set out as a note under section 426 of this title.

**Effective Date of 1982 Amendment**

Amendment by section 101(a)(2) of Pub. L. 97–248 applicable to cost reporting periods beginning on or after Oct. 1, 1982, see section 101(b)(1) of Pub. L. 97–248, set out as an Effective Date note under section 1395ww of this title.

Section 102(b) of Pub. L. 97–248, as amended by Pub. L. 98–21, title VI, § 605(a), Apr. 20, 1983, 97 Stat. 199, provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to cost reporting periods beginning on or after October 1, 1983."

Section 103(b) of Pub. L. 97–248 provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to any costs incurred after the enactment of this Act [Sept. 3, 1982]."


Section 109(b)(3) of Pub. L. 97–248 provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to any costs incurred after 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 [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 [this chapter] 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 1395v, 1395c, and 1395uu of this title and section 162 of Title 26) shall be effective as if it had been originally included as a part of that provision of the Social Security Act or Internal Revenue Code of 1986 to which it relates, as such provision of such Act or Code was amended by the Omnibus Budget Reconciliation [Reconciliation] Act of 1981 [Pub. L. 97–35]."

"(3) The amendments made by subsection (d) [amending this section and sections 1395u, 1395bb, 1395cc, and 1395gg of this title] shall take effect upon enactment [Sept. 3, 1982]."

Amendment by section 148(b) of Pub. L. 97–248 effective with respect to contracts entered into on or after the first day of the first month beginning after the date of the enactment of this Act Aug. 13, 1981.

Amendment by section 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(c)(1) of Pub. L. 97–35, set out as a note under section 1396d of this title.

Section 214(c) of Pub. L. 97–35 provided that:

"(1) Subject to paragraph (2), the amendment made by subsection (a) [amending this section] shall apply to cost reporting periods ending after September 30, 1981.

"(2) In the case of a cost reporting period beginning before October 1, 1981, any reduction in payments resulting from the amendment made by subsection (a) shall be imposed only in proportion to the part of the period that occurs after September 30, 1981."

Section 214(b) of Pub. L. 97–35, as amended by Pub. L. 97–248, title I, § 128(c)(1), Sept. 3, 1982, 96 Stat. 367, provided that:

"(1) Subject to paragraph (2), the amendment made by subsection (a) [amending this section] shall apply to cost reporting periods ending after September 30, 1981.

"(2) In the case of a cost reporting period beginning before October 1, 1981, any reduction in payments resulting from the amendment made by subsection (a) shall be imposed only in proportion to the part of the period that occurs after September 30, 1981."

For effective date, savings, and transitional provisions relating to amendments by section 213(b) of Pub. L. 97–35, see section 2114 of Pub. L. 97–35, set out as a note under section 701 of this title.

**Effective Date of 1980 Amendments**

Amendment by Pub. L. 96–611 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96–611, set out as a note under section 1395b of this title.

Section 902(c) of Pub. L. 96–499 provided that: "The amendments made by this section [amending this section and sections 1338c–7 and 1396a of this title] shall become effective on the date of (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]."

Section 930(s) of Pub. L. 96–499 provided that:

"(1) the amendments made by this section [amending this section, sections 426, 1395c, 1395d, 1395f, 1395m, 1395x, 1395n, and 1395m of this title, and section 231(f) of Title 45, Railroads, and repealing section 1395m of this title] shall become effective with respect to services furnished on or after July 1, 1981, except that the amendments made by subsections (n)(1) and (o) [amending this section and section 1395b 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 im-
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 1395f of this title.

Amendment by section 938(a) of Pub. L. 96–499 applicable with respect to services provided on or after July 1, 1981, see section 936(d) of Pub. L. 96–499, set out as a note under section 1395f of this title.

Section 937(c) of Pub. L. 96–499, as amended by Pub. L. 98–369, div. B, title III, §2534(c)(1)(B), July 18, 1984, 98 Stat. 1102, provided that: “The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1984.”

Section 948(c)(1) of Pub. L. 96–499 provided that: “The amendments made by subsection (a) [amending this section and section 1395k of this title] shall apply with respect to cost accounting periods beginning on or after October 1, 1978. A hospital’s election under section 1861(b)(7)(A) of the Social Security Act [subsec. (b)(7)(A) of this section] respect to a complete tax year in accordance with section 15 of Public Law 93–233 as of September 30, 1978, shall constitute such hospital’s election under such section (as amended by subsection (a)(1)) on and after October 1, 1978, until otherwise provided by the hospital.”

Section 951(c) of Pub. L. 96–499 provided that: “The amendments made by this section [amending this section] shall take effect on January 1, 1981.”

**Effective Date of 1978 Amendment**

Amendment by Pub. L. 95–292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 30, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility’s or provider’s first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as a note under section 426 of this title.

**Effective Date of 1977 Amendments**

Section 501(c) of Pub. L. 95–216 provided that: “The amendments made by this section [amending this section and section 1395a of this title] shall be effective in the case of items and services furnished after the date of the enactment of this Act [Dec. 20, 1977].”

Amendment by Pub. L. 95–210 applicable to services rendered on or after the first day of the third calendar month which begins after Dec. 31, 1977, see section 1(i) of Pub. L. 95–210, set out as a note under section 1395k of this title.

Amendment by section 3(a)(2) of Pub. L. 95–142 effective Oct. 1, 1977, see section 5(e) of Pub. L. 95–142, set out as an Effective Date note under section 1320a-3 of this title.

Amendment by section 19(b)(1) of Pub. L. 95–142 effective with respect to operation of a hospital, skilled nursing facility, or intermediate care facility on and after the first day of its first fiscal year which begins after the end of the six-month period beginning on the date of enactment of this Act (Oct. 30, 1972) a uniform reporting and uniform reporting and recording system is established under section 1320a(a) of this title for that type of health services facility, except that for other types of facilities or organizations effective with respect to operations on and after the first day of its first fiscal year which begins after such date as the Secretary determines to be appropriate for the implementation of the reporting requirement for that type of facility or organization, see section 19(c)(2) of Pub. L. 95–142, set out as a note under section 1396a of this title.

Section 21(c)(1) of Pub. L. 95–142 provided that: “The amendments made by subsection (a) [amending this section] shall be effective on the first day of the first calendar quarter which begins more than six months after the date of enactment of this Act [Oct. 25, 1972].”

**Effective Date of 1975 Amendment**

Section 106(b) of Pub. L. 94–182 provided that: “Subject to subsection (c) [enacting provisions set out below], the amendment made by subsection (a) [amending this section] shall be effective on the first day of the sixth month which begins after the date of enactment of this Act [Dec. 31, 1975].”

Section 112(d) of Pub. L. 94–182 provided that: “The amendments made by this section [amending this section and sections 1395–cc and 1395f of this title] shall be effective with respect to utilization review activities conducted on and after the first day of the first month which begins more than 30 days after the date of enactment of this Act [Dec. 31, 1975].”

**Effective Date of 1972 Amendment**

Amendment by section 211(b), (c)(2) of Pub. L. 92–603 applicable to services furnished with respect to admissions occurring after Dec. 31, 1972, see section 211(d) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Section 223(b) of Pub. L. 92–603 provided that: “The amendments made by this section [amending this section and section 1395cc of this title] shall be effective with respect to accounting periods beginning after Dec. 31, 1972.”

Section 227(g) of Pub. L. 92–603 provided that: “The amendments made by this section [amending this section and sections 1395f, 1395k, 1395n, 1395u, and 1395cc of this title] shall apply with respect to accounting periods beginning after June 30, 1973.”

Section 234(i) of Pub. L. 92–603 provided that: “The amendments made by this section [amending this section and sections 1395f, 1395k, 1395n, and 1395cc of this title] shall apply with respect to any provider of services for fiscal years (of such provider) beginning after the fifth month following the month in which this Act is enacted (October 1972).”

Section 246(c) of Pub. L. 92–603 provided that: “The amendments made by this section [amending this section and section 1396 of this title] shall be effective July 1, 1973.”

Section 251(d) of Pub. L. 92–603, as amended by Pub. L. 93–233, §17(a), Dec. 31, 1973, 87 Stat. 967, provided that:

“(1) The amendments made by subsection (a) [amending this section and section 1395f and 1395k of this title] shall apply with respect to services furnished on or after July 1, 1973.

“(2) The amendments made by subsection (b) [amending this section and section 1395n of this title] shall apply with respect to services furnished on or after the date of enactment of this Act [Oct. 30, 1972].

“(3) The amendments made by subsection (c) [amending this section] shall be effective with respect to accounting periods beginning after the month in which there are promulgated, by the Secretary of Health, Education, and Welfare, final regulations implementing the provisions of section 1861(v)(6) of the Social Security Act [subsec. (v)(6) of this section].”

Section 252(b) of Pub. L. 92–603 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 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 230(d) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Section 264(b) of Pub. L. 92–603 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]."

Section 272(b) of Pub. L. 92–603 provided that: "The amendments made by this section [amending this section] shall be effective with respect to services furnished after June 30, 1973."

Section 276(b) of Pub. L. 92–603 provided that: "The amendment made by this section [amending this section] shall apply with respect to accounting periods beginning after December 31, 1972."

Amendment by section 283(a) of Pub. L. 92–603 to apply with respect to services rendered after Dec. 31, 1972, see section 283(c) of Pub. L. 92–603, set out as a note under section 1395n of this title.

**Effective Date of 1968 Amendment**

Section 127(c) of Pub. L. 90–248 provided that: "The amendments made by subsections (a) and (b) [amending this section and section 1395f of this title] shall apply with respect to services furnished after December 31, 1967."

Amendment by section 129(a), (b), (c)(9)(C), (10), (11) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 129(d) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Amendment by section 132(a) of Pub. L. 90–248 applicable with respect to items purchased after Dec. 31, 1967, see section 132(c) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Amendment by section 133(a), (b) of Pub. L. 90–248 applicable with respect to services furnished after June 30, 1968, see section 133(g) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Section 134(b) of Pub. L. 90–248 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to services furnished after December 31, 1967."

Amendment by section 143(a) of Pub. L. 90–248 effective July 1, 1966, see section 143(d) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Section 144(e) of Pub. L. 90–248 provided that: "The amendments made by this section [amending this section] shall apply with respect to services furnished after March 31, 1968."

**Effective Date of 1966 Amendment**

Amendment by Pub. L. 89–713 effective Nov. 2, 1966, see section 6 of Pub. L. 89–713, set out as a note under section 6091 of Title 26, Internal Revenue Code.

**Construction of 2008 Amendment**


**Conforming References to Previous Part D**

Pub. L. 108–173, title I, §101(e)(1), Dec. 8, 2003, 117 Stat. 2150, provided that: "Any reference in law (in effect before the date of the enactment of this Act [Dec. 8, 2003]) to part D of title XVIII of the Social Security Act [part D of this subchapter] is deemed a reference to part E of such title [this part] (as in effect after such date)."

**Application of 2003 Amendment to Physician Specialties**

Amendment by section 303 of Pub. L. 108–173, insofar as applicable to payments for drugs or biologicals and drug administration services furnished by physicians, is applicable only to physicians in the specialties of hematology, hematology/oncology, and medical oncology under this subchapter, see section 303(j) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

**Frontier Extended Stay Clinic Demonstration Project**


"(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) Specific Code.—The Secretary shall determine the appropriate life-safety codes for such clinics that treat patients for needs referred to in subsection (b)(2).

"(d) Funding.—

"(1) In General.—Subject to paragraph (2), there are authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as are necessary to conduct the demonstration project under this section.

"(2) Budget Neutral Implementation.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration project under this section was not implemented.

"(e) Three-Year Period.—The Secretary shall conduct the demonstration under this section for a 3-year period.

"(f) Report.—Not later than the date that is 1 year after the date on which the demonstration project concludes, the Secretary shall submit to Congress a report on the demonstration project, together with such recommendations for legislation or administrative action as the Secretary determines appropriate.

"(g) Definitions.—In this section, the terms ‘hospital’ and ‘critical access hospital’ have the meanings given such terms in subsections (e) and (mm), respectively, of section 1391 of the Social Security Act (42 U.S.C. 1395x)."

**MedPAC Study of Coverage of Surgical First Assistant 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 ad-
visability of providing for payment under part B of title XVIII of the Social Security Act [part B of this subchapter] for surgical first assisting services furnished by a certified registered nurse first assistant to Medicare beneficiaries.

“(b) Report.—Not later than January 1, 2005, the Commission shall submit to Congress a report on the study conducted under subsection (a) together with recommendations for such legislation or administrative action as the Commission determines to be appropriate.

“(c) Definitions.—In this section:

“(1) Surgical first assisting services.—The term ‘surgical first assisting services’ means services consisting of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care (as determined by the Secretary of Health and Human Services) furnished by a certified registered nurse first assistant (as defined in paragraph (2)) which the certified registered nurse first assistant is legally authorized to perform by the State in which the services are performed.

“(2) Certified registered nurse first assistant.—The term ‘certified registered nurse first assistant’ means an individual who:

“(A) is a registered nurse and is licensed to practice nursing in the State in which the surgical first assisting services are performed;

“(B) has completed a minimum of 2,000 hours of first assisting a physician with surgery and related preoperative, intraoperative, and postoperative care; and

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

STUDIES RELATING TO VISION IMPAIRMENTS


“(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 vision therapist.

“(b) Report on Appropriateness of a Demonstration Project to Test Feasibility of Using PPO Networks To Reduce Costs of Acquiring Eyeglasses for Medicare Beneficiaries After Cataract Surgery.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall submit to Congress a report on the feasibility of establishing a two-year demonstration project under which the Secretary enters into arrangements with vision care providers 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; and

“(B) diagnostic and other services that a chiropractor is legally authorized to perform by the State or jurisdiction in which such treatment is provided.

“(2) Demonstration Project.—The term ‘demonstration project’ means a demonstration project established by the Secretary under subsection (b)(1).

“(3) Eligible beneficiary.—The term ‘eligible beneficiary’ means an individual who is enrolled under part B of the medicare program.

“(4) Medicare Program.—The term ‘medicare program’ means the health benefits program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

“(b) Demonstration of Coverage of Chiropractic Services Under Medicare.—

“(1) Establishment.—The Secretary shall establish demonstration projects in accordance with the provisions of this section for the purpose of evaluating the feasibility and advisability of covering chiropractic services under the medicare program (in addition to the coverage provided for services consisting of treatment by means of manual manipulation of the spine to correct a subluxation described in section 1861(r)(5) of the Social Security Act (42 U.S.C. 1395x(r)(5))).

“(2) No Physician Approval Required.—In establishing the demonstration projects, the Secretary shall ensure that an eligible beneficiary who participates in a demonstration project, including an eligible beneficiary who is enrolled for coverage under a Medicare+Choice plan (or, on and after January 1, 2006, under a Medicare Advantage plan), is not required to receive approval from a physician or other health care provider in order to receive a chiropractic service under a demonstration project.

“(3) Consultation.—In establishing the demonstration projects, the Secretary shall consult with 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.

“(c) Conduct of Demonstration Projects.—

“(1) Demonstration sites.—

“(A) Selection of Demonstration Sites.—The Secretary shall conduct demonstration projects at 4 demonstration sites.

“(B) Geographic Diversity.—Of the sites described in subparagraph (A)—

“(i) two shall be in rural areas; and

“(ii) two shall be in urban areas.

“(C) Sites located in HPSAs.—At least 1 site described in clause (i) of subparagraph (B) and at least 1 site described in clause (ii) of such subparagraph shall be located in an area that is designated under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254c(a)(1)(A)) as a health professional shortage area.

“(2) Implementation; Duration.—

“(A) Implementation.—The Secretary shall not implement the demonstration projects before October 1, 2004.

“(B) Duration.—The Secretary shall complete the demonstration projects by the date that is 2 years after the date on which the first demonstration project is implemented.

“(d) Evaluation and Report.—

“(1) Evaluation.—The Secretary shall conduct an evaluation of the demonstration projects.

“(A) to determine whether eligible beneficiaries who use chiropractic services use a lesser overall
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amount of items and services for which payment is made under the medicare program than eligible beneficiaries who do not use such services;
ushing to the cost of providing payment for chiropractic services under the medicare program;
"(C) to determine the satisfaction of eligible beneficiaries participating in the demonstration projects and the quality of care received by such beneficiaries; and
"(D) to evaluate such other matters as the Secretary determines is appropriate.

(2) REPORT.—Not later than the date that is 1 year after the date on which the demonstration projects conclude, the Secretary shall submit to Congress a report on the evaluation conducted under paragraph (1) together with such recommendations for legislation or administrative action as the Secretary determines is appropriate.

(e) WAIVER OF MEDICARE REQUIREMENTS.—The Secretary shall waive compliance with such requirements of the medicare program to the extent and for the period the Secretary finds necessary to conduct the demonstration projects.

(f) FUNDING.—

(1) DEMONSTRATION PROJECTS.—

In general.—Subject to subparagraph (B) and paragraph (2), the Secretary shall provide for the transfer from the Federal Supplementary Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395 et seq.) of such funds as are necessary for the costs of carrying out the demonstration projects under this section.

(2) LIMITATION.—In conducting the demonstration projects under this section, the Secretary shall ensure that the aggregate payments made by the Secretary under the medicare program do not exceed the amount which the Secretary would have paid under the medicare program if the demonstration projects under this section were not implemented.

(2) EVALUATION AND REPORT.—There are authorized to be appropriated such sums as are necessary for the purpose of developing and submitting the report to Congress under subsection (d).

DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND


(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 [part B of this subchapter] under which medicare beneficiaries with chronic conditions described in subsection (b) are 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.

(f) WAIVER AUTHORITY.—The Secretary shall provide for the costs to the medicare program for the provision of such services that is directly attributable to such clarification.

(g) REPORT TO CONGRESS.—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.

(h) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e). The report shall include the following:

"(1) An examination of whether the provision of home health services to medicare beneficiaries under the project has had any of the following effects:

"(A) Has adversely affected the provision of home health services under the medicare program.

"(B) Has directly caused an increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification.

"(2) The specific data evidencing the amount of any increase in expenditures that is directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program.

"(3) Specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency, and purpose of their absences from the home to qualify for home health services without incurring additional costs to the medicare program.

(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(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 [part B of this subchapter].

"(2) HOME HEALTH SERVICES.—The term ‘home health services’ has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

"(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term ‘activities of daily living’ means eating, toileting, transferring, bathing, and dressing.

INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOSPITAL DISCHARGE PLANS

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**


"(1) IN GENERAL.—The Secretary of Health and Human Services shall promptly issue (without regard to chapter 8 of title 5, United States Code) such regulations or program memoranda as may be necessary to effect the amendments made by this section [amending this section, sections 1395r and 1395ff 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)(i) of the Social Security Act [subsec. (v)(1)(L)(i) of this section] for such periods shall be the national standardized per beneficiary limitation specified in Table 3B 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 [subsec. (v)(1)(L)(v)(i) of this section] for a census division shall be the sum of the labor and nonlabor components of the standardized per beneficiary limitation for that census division specified in Table 3B published in the Federal Register on that date (63 FR 42926) (or in Table 3D as so published with respect to Puerto Rico and Guam), and adjusted to reflect variations in wages among different geographic areas as specified in Tables 4a and 4b published in the Federal Register on that date (63 FR 42926–42933).

"(B) PER VISIT LIMITS.—In effecting the amendments made by subsection (b) [amending this section] for cost reporting periods beginning in fiscal year 1999, the limits determined under section 1861(v)(1)(L)(i)(V) of such Act [subsec. (v)(1)(L)(i)(V) of this section] 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 100%, and adjusted to reflect variations in wages among different geographic areas as specified in Tables 4a and 4b published in the Federal Register on August 11, 1998 (63 FR 42926–42933).

**STUDY ON EXPANSION OF MEDICAL NUTRITION THERAPY SERVICES BENEFIT**

**Pub. L. 106–554, § 1(a)(6) [title I, § 105(i)], Dec. 21, 2000, 114 Stat. 2763, 2763A–472, 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 for 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 [this subchapter] for some or all Medicare beneficiaries.

"(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall submit a report on the findings of the study conducted under subsection (a) to the Committee on Ways and Means and the Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate.

**GOA STUDY ON COVERAGE OF SURGICAL FIRST ASSISTING SERVICES OF CERTIFIED REGISTERED NURSE FIRST ASSISTANTS**

**Pub. L. 106–554, § 1(a)(6) [title IV, § 435], 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 [this subchapter] 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 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 compensating, training, 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.—

"(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 [this subchapter] for services provided by—

"(A) surgical technologist;

"(B) marriage counselor;

"(C) marriage and family therapist;

"(D) pastoral care counselor; and

"(E) licensed professional counselor of mental health.

"(2) COSTS TO PROGRAM.—The study shall consider the short-term and long-term benefits, and costs to the Medicare program, of providing the coverage described in paragraph (1).

"(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Commission shall submit to Congress a report on the study conducted under subsection (a), together with any recommendations for legislation that the Commission determines to be appropriate as a result of such study.

**DEVELOPMENT OF PATIENT ASSESSMENT INSTRUMENTS**

**Pub. L. 106–554, § 1(a)(6) [title V, § 545], Dec. 21, 2000, 114 Stat. 2763, 2763A–551, provided that:*

"(a) DEVELOPMENT.—

"(1) IN GENERAL.—Not later than January 1, 2005, the Secretary of Health and Human Services shall submit to the Committee on Ways and Means and the
Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate a report on the development of standard instruments for the assessment of the health and functional status of patients, for whom items and services described in subsection (b) are furnished, and include in the report a recommendation on the use of such standard instruments for payment purposes.

"(2) Design for Comparison of Common Elements.—The Secretary shall design such standard instruments in a manner such that—

"(A) elements that are common to the items and services described in subsection (b) may be readily comparable and are statistically compatible; and

"(C) the standard instruments supersede any other assessment instrument used before that date.

"(3) Consultation.—In developing an assessment instrument under paragraph (1), the Secretary shall consult with the Medicare Payment Advisory Commission, the Agency for Healthcare Research and Quality, and qualified organizations representing providers of services and suppliers under title XVIII of this subchapter.

"(b) Description of Services.—For purposes of subsection (a), items and services described in this subsection are those items and services furnished to individuals entitled to benefits under part A, or enrolled under part B, or both of title XVIII of the Social Security Act [part A or part B of this subchapter] for which payment is made under such title [this subchapter], 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.

"(c) Conforming References to Previous Part C Section 4002(c)(1) of Pub. L. 105–33 provided that: "Any reference in law (in effect before the date of the enactment of this Act [Aug. 5, 1997]) to part C of title XVIII of the Social Security Act [part A or part B of this subchapter] is deemed a reference to part D of such title [this part] (as in effect after such date)."

"(d) Deadline for Publication of Determination on Coverage of Screening Barium Enema Section 4109(a)(2) of Pub. L. 105–33 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."

"(e) Establishment of Outcome Measures for Beneficiaries With Diabetes Section 4109(c) of Pub. L. 105–33 provided that: "(1) In General.—The Secretary of Health and Human Services, in consultation with appropriate organizations, shall establish outcome measures, including glycosolated 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.

"(f) Vaccines Outreach Expansion Section 4109 of Pub. L. 105–33 provided that: "(a) Extension of Influenza and Pneumococcal Vaccination Campaign.—In order to increase utilization of pneumococcal and influenza vaccines in medicare beneficiaries, the Influenza and Pneumococcal Vaccination Campaign carried out by the Health Care Financing Administration in conjunction with the Centers for Disease Control and Prevention and the National Coalition for Adult Immunization, is extended until the end of fiscal year 2002.

"(b) Authorization of Appropriation.—There are hereby authorized to be appropriated for each of fiscal years 1998 through 2002, $8,000,000 for the Campaign described in subsection (a). Of the amount so authorized to be appropriated in each fiscal year, 60 percent of the amount so appropriated shall be payable from the Federal Hospital Insurance Trust Fund, and 40 percent shall be payable from the Federal Supplementary Medical Insurance Trust Fund."

"(g) Study on Preventive and Enhanced Benefits Section 4108 of Pub. L. 105–33 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 to the analysis to Congress.

"(h) Utilization Guidelines Section 4513(c) of Pub. L. 105–33 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 [part B of this subchapter] in cases in which a subluxation has not been demonstrated by X-ray to exist."

"(i) Authorizing Payment for Paramedic Interceptor Service Providers in Rural Communities Pub. L. 105–33, title IV, § 4531(c), Aug. 5, 1997, 111 Stat. 452, as amended by Pub. L. 106–113, div. B, § 1000(a)(6) (title IV, § 412(a)), Nov. 29, 1999, 113 Stat. 1536, 1501A–377, provided that: "In promulgating regulations to carry out section 1861(a)(7) of the Social Security Act (42 U.S.C. 1395x(a)(7)) with respect to the coverage of ambulance service, the Secretary of Health and Human Services may include coverage of advanced life support services (in this subsection referred to as ‘ALS intercept services’) provided by a paramedic intercept service provider in a rural area if the following conditions are met:

"(1) The ALS intercept services are provided under a contract with one or more volunteer ambulance services and are medically necessary based on the health condition of the individual being transported.

"(2) The volunteer ambulance service involved—

"(A) is certified as qualified to provide ambulance service for purposes of such section,

"(B) provides only basic life support services at the time of the intercept, and

"(C) is prohibited by State law from billing for any services.

"(3) The entity supplying the ALS intercept service—

"(A) is certified as qualified to provide such services under the medicare program under title XVIII of the Social Security Act (this subchapter), and

"(B) bills all recipients who receive ALS intercept services from the entity, regardless of whether or not such recipients are medicare beneficiaries.
For purposes of this subsection, an area shall be treated as a rural area if it is designated as a rural area by any law or regulation of the State or if it is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification, originally published in the Federal Register on February 27, 1982 (57 Fed. Reg. 6723)).

Section 4601(b) of Pub. L. 105-33 provided that: "The Secretary of Health and Human Services shall not consider the amendment made by subsection (a) [amending this section] in making any exemptions and exceptions pursuant to section 1861(v)(1)(L)(ii) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(ii))."

STUDY ON DEFINITION OF HOMEBOUND

Section 4613 of Pub. L. 105-33 provided that: "(a) Study.—The Secretary of Health and Human Services shall conduct a study of the criteria that should be applied, and the method of applying such criteria, in the determination of whether an individual is homebound for purposes of qualifying for receipt of benefits for home health services under the medicare program.

(b) Report.—Not later than October 1, 1996, the Secretary shall submit a report to Congress on the study conducted under subsection (a). The report shall include specific recommendations on such criteria and methods."
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 medical education program, an institution that has a doctor of dental surgery or of dental medicine serving as its medical director shall be considered to meet such requirement if the laws of the State in which the institution is located locate 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

Section 6205(a)(1)(A) of Pub. L. 101–239 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 [this subchapter] 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, on the immediate grounds of the hospital." 

Section 6205(a)(2) of Pub. L. 101–239 provided that: "Paragraph (1)(A) [set out above] shall apply with respect to costs for organization and conduct of the medical staff of a nursing school 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, on the immediate grounds of the hospital." 

DISSEMINATION OF RURAL HEALTH CLINIC INFORMATION

Section 6213(e) of Pub. L. 101–239 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

Section 6213(f) of Pub. L. 101–239 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 [subsec. (a)(2) of this section] if the facility is located on an island and would otherwise be qualified to be certified as such a facility but for the requirement that the services of a physician assistant or nurse practitioner be provided in the facility." 

CONTINUED USE OF HOMER HEALTH WAGE INDEX IN EFFECT PRIOR TO JULY 1, 1989, UNTIL AFTER JULY 1, 1991

Section 6222 of Pub. L. 101–239 provided that: "Notwithstanding the requirement of section 1861(v)(1)(L)(iii) of the Social Security Act [subsec. (v)(1)(L)(iii) of this section], the Secretary of Health and Human Services shall, in determining the limits of reasonable costs under title XVIII of the Social Security Act [this subchapter] with respect to services furnished by home health agencies, continue to utilize the wage index that was in effect for cost reporting periods beginning before July 1, 1989, until cost reporting periods beginning on or after July 1, 1991."

PAYMENT FOR MEDICAL ESCORT OR MEDICAL ATTENDANT ON COMMERCIAL AIRLINER ALLOWED

Section 4247 of Pub. L. 100–647 provided that: "(a) In General.—The Secretary of Health and Human Services shall provide that in cases where (as of the date of the enactment of this Act [Nov. 10, 1988]) transportation on a commercial airliner is covered under section 1861(s)(7) of the Social Security Act [subsec. (s)(7) of this section], 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

Section 411(i)(2)(E) of Pub. L. 100–647 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(i) of the Social Security Act [subsec. (i) of this section] is deemed to include the requirement described in section 1819(c)(3)(A) of such Act [section 1395i–3(c)(3)(A) of this title] (as added by section 4201(a)(3) of OBRA)."

MORATORIUM ON PRIOR AUTHORIZATION FOR HOME HEALTH AND POST-HOSPITAL EXTENDED CARE SERVICES

Section 4129(e) of Pub. L. 100–203 provided that: "The Secretary of Health and Human Services shall 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 [part A or B of this subchapter] at any time prior to six months after the date on which the Congress receives the report required under section 9305(k)(4) of the Omnibus Budget Reconciliation Act of 1986 [section 9305(k)(4) of Pub. L. 99–509, set out below]."

DELAY IN PUBLISHING REGULATIONS WITH RESPECT TO DESIGNATION OF ENTITIES

Section 4139(f) of Pub. L. 100–203 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 [subsec. (u) of this section]) for purposes of title XVIII of such Act [this subchapter]—

"(1) on any date prior to 6 months after the date on which the Secretary has published a proposed rule with respect to the deeming of the entity, and

"(2) until the Secretary publishes a final rule with respect to the deeming of the entity." 

DEVELOPMENT OF UNIFORM NEEDS ASSESSMENT INSTRUMENT

Section 9305(h) of Pub. L. 99–509 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

Section 9305(k) of Pub. L. 99–509 directed Secretary of Health and Human Services to conduct a demonstration program concerning prior and concurrent authorization for post-hospital extended care services and home health services furnished under part A or part B of this subchapter, which was to include at least four projects and was to be initiated by not later than Jan. 1, 1987, under which the Secretary was to monitor the acceptance of individuals entitled to benefits under this subchapter by providers to ensure that the placement of such individuals was not delayed until the re-
suitable 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**

Section 9315(b) of Pub. L. 99–509 provided that: “In establishing limitations under section 1861(v)(1)(L) of the Social Security Act [subsec. (v)(1)(L) of this section] on payment for home health services for cost reporting periods beginning on or after July 1, 1986, the Secretary of Health and Human Services shall—

1. base such limitations on the most recent data available, which 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 services, and verification procedures that result from the Secretary’s changing the requirements for such procedures, to the extent the changes in costs are not reflected in such data.

Paragraph (2) shall apply to changes in requirements effected before, on, or after July 1, 1986.”

**Comptroller General Study and Report on Cost Limits for Home Health Services**

Section 9315(c) of Pub. L. 99–509 directed Comptroller General to study and report to Congress, not later than Jan. 1, 1989, on the appropriateness and impact on medicare beneficiaries of applying the per visit cost limits for home health services furnished by a hospital and skilled nursing facilities effective before, on, or after July 1, 1986.”

**Reduction in Payment To Avoid Duplicate Payment for Services of Physician Assistants**

Section 9338(d) of Pub. L. 99–509 directed Secretary of Health and Human Services to reduce the amount of payment that would otherwise be made to hospitals and skilled nursing facilities under this subchapter to eliminate estimated duplicate payments for historical or current costs allocable to services furnished by an agency, and appropriateness of the percentage limits so established.

**Elimination of Private Room Subsidy**

Section 111 of Pub. L. 99–509 provided that:

“(a) The Secretary of Health and Human Services shall—

1. pursuant to section 1861(v)(2) of the Social Security Act [subsec. (v)(2) of this section], not allow as a reasonable cost the estimated amount of which the costs incurred by a hospital or skilled nursing facility for nonmedically necessary private accommodations for medicare beneficiaries exceeds the costs which would have been incurred by such hospital or facility for semiprivate accommodations.

(b) The Secretary of Health and Human Services shall—

1. pursuant to section 1861(v)(2) of the Social Security Act [subsec. (v)(2) of this section], not allow as a reasonable cost the estimated amount of which the costs incurred by a hospital or skilled nursing facility for nonmedically necessary private accommodations for medicare beneficiaries exceeds the costs which would have been incurred by such hospital or facility for semiprivate accommodations.

2. provide opportunity for public comment, and appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than January 31, 1983.”

**Regulations Regarding Access to Books and Records**

Section 952(b) of Pub. L. 96–499, as added by Pub. L. 97–248, title I, § 127(2), Sept. 3, 1982, 96 Stat. 366, provided that: “Unless the Secretary of Health and Human Services first publishes final regulations prescribing the criteria and procedures described in the last sentence of section 1861(v)(1)(I) of the Social Security Act [subsec. (v)(1)(I) of this section] by January 1, 1983, after providing a period of not less than 60 days for public comment on proposed regulations, the amendment made by subsection (a) [amending this section] shall apply only to books, documents, and records relating to services furnished (pursuant to contract or subcontract) on or after the date on which final regulations of the Secretary are first published.”

**Compliance With the Life Safety Code or State Fire and Safety Code**

Section 915(b) of Pub. L. 96–499 provided that: “Any institution (or part of an institution) which complied with the requirements of section 1861(v)(13) of the Social Security Act [subsec. (v)(13) of this section] on the day before the date of the enactment of this Act [Dec. 5, 1980] shall, so long as such compliance is maintained (either by meeting the applicable provisions of the Life Safety Code [21st edition, 1967, or 23rd edition, 1973], or with or without waivers of specific provisions, or by...”
meeting the applicable provisions of a fire and safety code imposed by State law as provided for in such section 1861(j)(13), be considered, for the purposes of titles XVIII or XIX of such Act [this subchapter or subchapter XIX of this chapter] to be in compliance with the requirements of such section 1861(j)(13), as it is amended by subsection (a) of this section."

Section 1396(c) of Pub. L. 95–182 provided that: "Any institution (or part of an institution) which complied with the requirements of section 1861(j)(13) of the Social Security Act [subsec. (j)(13) of this section] on the day preceding the first day referred to in subsection (b) [enacting provisions set out as a note under this section] shall, so long as such compliance is maintained (either by meeting the applicable provisions of the Life Safety Code (21st edition, 1987) or with or without waivers of specific provisions, or by meeting the applicable provisions of a fire and safety code imposed by State law as provided for in such section 1861(j)(13)], be considered (for purposes of titles XVIII and XIX of such Act) [subchapters XVIII and XIX of this chapter] 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. Section 1(e) of Pub. L. 95–210 provided that: "Any private, nonprofit health care clinic that—

"(1) on July 1, 1977, was operating and located in an area which on that date (A) was not an urbanized area (as defined by the Bureau of the Census) and (B) had a supply of physicians insufficient to meet the needs of the area (as determined by the Secretary), and

"(2) meets the definition of a rural health clinic under section 1861(aa)(2) [subsec. (aa)(2) of this section] or section 1906(i) of the Social Security Act [section 1906(i) of this title], except for clause (l) of section 1861(aa)(2) [subsec. (aa)(2) of this section],

shall be considered, for the purposes of title XVIII or XIX, respectively, of the Social Security Act [this subchapter or subchapter XIX of this chapter], as satisfying the definition of a rural health clinic under such section."

PROMULGATION OF REGULATIONS DEFINING COSTS CHARGABLE TO PERSONAL FUNDS OF PATIENTS IN SKILLED NURSING FACILITIES: DATE OF ISSUANCE. Section 21(b) of Pub. L. 95–142 provided that: "The Secretary of Health, Education, and Welfare [now Health and Human Services] shall, by regulation, define those costs which may be charged to the personal funds of patients in skilled nursing facilities who are individuals receiving benefits under the provisions of title XVIII [this subchapter], or under a State plan approved under the provisions of title XIX [subchapter XIX of this chapter], of the Social Security Act, and those costs which are to be included in the reasonable cost or reasonable charge for extended care services as determined under the provisions of title XVIII, or for skilled nursing and intermediate care facility services as determined under the provisions of title XIX, of such Act."

[Section 21(c)(2) of Pub. L. 95–142 provided that: "The Secretary of Health, Education, and Welfare shall issue the regulations required under subsection (b) [set out above] within ninety days after the date of enactment of this Act (Oct. 25, 1977)."]


PAYMENT FOR SERVICE OF PHYSICIANS RENDERED IN A TEACHING HOSPITAL FOR ACCOUNTING PERIODS BEGINNING AFTER JUNE 30, 1975, AND PRIOR TO OCTOBER 1, 1978; STUDIES, REPORTS, ETC.; EFFECTIVE DATES. Pub. L. 93–233, §15(a)(1), (b)–(d), Dec. 31, 1973, 87 Stat. 965, as amended by Pub. L. 93–388, §7, Aug. 7, 1974, 88 Stat. 422; Pub. L. 94–368, §7, Oct. 16, 1976, 90 Stat. 1959; Pub. L. 95–292, §7, June 13, 1978, 92 Stat. 316, provided that for the cost accounting periods beginning after June 30, 1975, and prior to October 1, 1978, subsec. (b) of this section will be administered as if paragraph (7) of subsec. (b) read as follows: "(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this title [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 title [this subchapter]". provided for studies with respect to methods of reimbursement for physicians’ services under subchapters XVIII and XIX of this chapter in hospitals which have a teaching program and a determination as to how and to what extent such funds are utilized, and provided that a final report be submitted to the Secretary of Health, Education, and Welfare, the Committee on Finance of the Senate, and the Committee on Ways and Means of the House of Representatives not later than Mar. 1, 1976.

PHYSICAL THERAPY SERVICES REQUIREMENTS; EFFECTIVE DATE POSTPONEMENT. Section 17(a) of Pub. L. 93–233 provided that: "In the administration of title XVIII of the Social Security Act [this subchapter], the amount payable thereunder with respect to physical therapy and other services referred to in section 1861(v)(5)(A) of such Act [subsec. (v)(5)(A) of this section] (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, final regulations implementing the provisions of section 1861(v)(5) of the Social Security Act [subsec. (v)(5)]."

PAYMENT FOR DURABLE MEDICAL EQUIPMENT. Section 245(a)–(c) of Pub. L. 92–603 provided that:

"(a) The Secretary is authorized to conduct reimbursement experiments designed to eliminate unreasonable expenses resulting from prolonged rentals of durable medical equipment described in section 1861(b)(6) of the Social Security Act [subsec. (b)(6) of this section]."

"(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 1833 of the Social Security Act [section 1395 of this title]) to purchase used equipment whenever the purchase price is at least 25 percent less than the reasonable charge for new equipment."

"(c) The Secretary is authorized, at such time as he deems appropriate, to implement on a nationwide basis
any such reimbursement procedures which he finds to be workable, desirable and economical and which are consistent with the purposes of this section.’’

Respecting the Rights of Hospital Patients to Receive Visitors and to Designate Surrogate Decision Makers for Medical Emergencies

Memorandum of President of the United States, Apr. 15, 2010, 75 F.R. 20511, provided:

Memorandum for the Secretary of Health and Human Services

There are few moments in our lives that call for greater compassion and companionship than when a loved one is admitted to the hospital. In these hours of need and moments of pain and anxiety, all of us would hope to have a hand to hold, a shoulder on which to lean—a loved one to be there for us, as we would be there for them.

Yet every day, all across America, patients are denied the kindnesses and caring of a loved one at their sides—whether in a sudden medical emergency or a prolonged hospital stay. Often, a widow or widower with no children is denied the support and comfort of a good friend. Members of religious orders are sometimes unable to choose someone other than an immediate family member to visit them and make medical decisions on their behalf. Also unjustly affected are gay and lesbian Americans who are often barred from the bedside of the partners with whom they may have spent decades of their lives—unable to be there for the person they love, and unable to act as a legal surrogate if their partner is incapacitated.

For all of these Americans, the failure to have their wishes respected concerning who may visit them or make medical decisions on their behalf has real consequences. It means that doctors and nurses do not always have the best information about patients’ medications and medical histories and that friends and certain family members are unable to serve as intermediaries to help communicate patients’ needs. It means that a stressful and at times terrifying experience for patients is senselessly compounded by indignity and unfairness. And it means that all too often, people are made to suffer or even to pass away alone, denied the comfort of companionship in their final moments while a loved one is left worrying and pacing down the hall.

Many States have taken steps to try to put an end to these problems. North Carolina recently amended its Patients’ Bill of Rights to give each patient “the right to designate visitors who shall receive the same visitation privileges as the patient’s immediate family members, regardless of whether the visitors are legally related to the patient”—a right that applies in every hospital in the State, Delaware, Nebraska, and Minnesota have adopted similar laws.

My Administration can expand on these important steps to ensure that patients can receive compassionate care and equal treatment during their hospital stay. By this memorandum, I request that you take the following steps:

1. Initiate appropriate rulemaking, pursuant to your authority under 42 U.S.C. 1395x and other relevant provisions of law, to ensure that hospitals that participate in Medicare or Medicaid respect the rights of patients to designate visitors. It should be made clear that designated visitors, including individuals designated by legally valid advance directives (such as durable powers of attorney and health care proxies), should enjoy visitation privileges that are no more restrictive than those that immediate family members enjoy. You should also provide that participating hospitals may not deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability. The rulemaking should take into account the need for hospitals to restrict visitation in medically appropriate circumstances as well as the clinical decisions that medical professionals make about a patient’s care or treatment.

2. Ensure that all hospitals participating in Medicare or Medicaid are in full compliance with regulations, codified at 42 CFR 482.13 and 42 CFR 489.102(a), promulgated to guarantee that all patients’ advance directives, such as durable powers of attorney and health care proxies, are respected, and that patients’ representatives otherwise have the right to make informed decisions regarding patients’ care. Additionally, I request that you issue new guidelines, pursuant to your authority under 42 U.S.C. 1395cc and other relevant provisions of law, and provide technical assistance on how hospitals participating in Medicare or Medicaid can best comply with the regulations and take any additional appropriate measures to fully enforce the regulations.

3. Provide additional recommendations to me, within 180 days of the date of this memorandum, on actions the Department of Health and Human Services can take to address hospital visitation, medical decision-making, or other health care issues that affect LGBT patients and their families.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

Barack Obama.

§ 1395y. Exclusions from coverage and medicaid 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 of this subchapter for any expenses incurred for items or services—

(1) (A) which, except for items and services described in a succeeding subparagraph or additional preventive services (as described in section 1395x(ddd)(1) of this title), are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member;

(B) in the case of items and services described in section 1395x(s)(10) of this title, which are not reasonable and necessary for the prevention of illness;

(C) in the case of hospice care, which are not reasonable and necessary for the palliation or management of terminal illness;

(D) in the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1395ww(e)(6) of this title;

(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

1 See References in Text note below.
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screening for glaucoma, which is performed more frequently than is provided under section 1395x(uu) of this title,

(G) in the case of prostate screening tests (as defined in section 1395x(qq) 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 1395(m)(4) 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–3(a)(6)(C) of this title for which payment is made under part B of this subchapter 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 of this subchapter,

(L) in the case of cardiovascular screening blood tests (as defined in section 1395x(x)(1) of this title), which are performed more frequently than is covered under section 1395x(x)(2) of this title,

(M) in the case of a diabetes screening test (as defined in section 1395x(yy)(1) of this title), which is performed more frequently than is covered under section 1395x(yy)(3) of this title,

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1395x(s)(2)(AA) of this title,

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1395x(ggg) of this title), which are furnished in excess of the number of sessions covered under paragraph (4) of such section, and

(P) in the case of personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title), which are performed more frequently than is covered under such section;

(2) for which the individual furnished such items or services has no legal obligation to pay, and which no other person (by reason of such individual's membership in a prepayment plan or otherwise) has a legal obligation to provide or pay for, except in the case of Federally qualified health center services;

(3) which are paid for directly or indirectly by a governmental entity (other than under this chapter and other than under a health plan or otherwise) has a legal obligation to provide or pay for, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(4) which are not provided within the United States 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 described in section 1395x(s)(8) of this title) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1395x(s)(10) of this title and subparagraph (B), (F), (G), (H), (K), or (P) of paragraph (1));

(8) where such expenses are for orthopedic shoes or other supportive devices for the feet, other than shoes furnished pursuant to section 1395x(s)(12) of this title;

(9) where such expenses are for custodial care (except, in the case of hospice care, as is otherwise permitted under paragraph (1)(C));

(10) where such expenses are for cosmetic surgery or are incurred in connection therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member;

(11) where such expenses constitute charges imposed by immediate relatives of such individual or members of his household;

(12) where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A of this subchapter in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services;

(13) where such expenses are for—

(A) the treatment of flat foot conditions and the prescription of supportive devices therefor,

(B) the treatment of subluxations of the foot, or

(C) routine foot care (including the cutting or removal of corns or calluses, the trimming of nails, and other routine hygienic care);

(14) which are other than physicians' services (as defined in regulations promulgated specifically for purposes of this paragraph), services described by section 1395x(s)(2)(K) of this title, certified nurse-midwife services,
qualified psychologist services, and services of a certified registered nurse anesthetist, and which are furnished to an individual who is a patient of a hospital or critical access hospital by an entity other than the hospital or critical access hospital, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the hospital or critical access hospital;

(15)(A) which are for services of an assistant at surgery in a cataract operation (including subsequent insertion of an intraocular lens) unless, before the surgery is performed, the appropriate utilization and quality control peer review organization (under part B of subchapter XI of this chapter) or a carrier under section 1395u of this title has approved of the use of such an assistant in the surgical procedure based on the existence of a complicating medical condition, or

(B) which are for services of an assistant at surgery to which section 1395w–4(1)(2)(B) of this title applies;

(16) in the case in which funds may not be used for such items and services under the Assisted Suicide Funding Restriction Act of 1997 (42 U.S.C. 14401 et seq.);

(17) where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1395w–3(a) of this title) by an entity other than an entity with which the Secretary has entered into a contract under section 1395w–3(b) of this title for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary;

(18) where such an item or service furnished by a skilled nursing facility services described in section 1395y(e)(2)(A)(i) of this title and which are furnished to an individual who is a resident of a skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1395x(s)(2)(D) of this title, which are furnished to such an individual without regard to such period), by an entity other than the skilled nursing facility, unless the services are furnished under arrangements (as defined in section 1395x(w)(1) of this title) with the entity made by the skilled nursing facility;

(19) which are for items or services which are furnished pursuant to a private contract described in section 1395a(b) of this title;

(20) in the case of outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services furnished as an incident to a physician’s professional services (as described in section 1395x(s)(2)(A) of this title), that do not meet the standards and conditions (other than any licensing requirement specified by the Secretary) under the second sentence of section 1395x(p) of this title (or under such sentence through the operation of subsection (g) or (l)(2) of section 1395x of this title) as such standards and conditions would apply to such therapy services if furnished by a therapist;

(21) where such expenses are for home health services (including medical supplies described in section 1395x(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section) furnished to an individual who is under a plan of care of the home health agency if the claim for payment for such services is not submitted by the agency;

(22) subject to subsection (h) of this section, for which a claim is submitted other than in an electronic form specified by the Secretary;

(23) which are the technical component of advanced diagnostic imaging services described in section 1395m(e)(1)(B) of this title for which payment is made under the fee schedule established under section 1395w–4(b) of this title and that are furnished by a supplier (as defined in section 1395x(d) of this title), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1395m(e)(2)(B) of this title;

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1395rr(b)(14) of this title) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services; or

(25) not later than January 1, 2014, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Paragraph (7) shall not apply to Federally qualified health center services described in section 1395x(aa)(3)(B) of this title. In making a national coverage determination (as defined in paragraph (1)(B) of section 1395ff(f) of this title) the Secretary shall ensure consistent with subsection (l) of this section that the public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.

(b) Medicare as secondary payer

(1) Requirements of group health plans

(A) Working aged under group health plans

(i) In general

A group health plan—

(I) may not take into account that an individual (or the individual’s spouse) who is covered under the plan by virtue of the individual’s current employment status with an employer is entitled to

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benefits under this subchapter under section 426(a) of this title, and

(ii) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) Exclusion of group health plan of a small employer

Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) Exception for small employers in multiemployer or multiple employer group health plans

Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) Exception for individuals with end stage renal disease

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

(iii) “Large group health plan” defined

In this subchapter, the term “large group health plan” has the meaning given such term in section 5000(b)(2) of the Internal Revenue Code of 1986, without regard to section 5000(d) of such Code.

(C) Individuals with end stage renal disease

A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is, or has been, entitled to or eligible for benefits under this subchapter under section 426-1 of this title during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A of this subchapter under the provisions of section 426-1 of this title, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 426-1 of this title if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this subchapter when an individual is entitled to or eligible for benefits under this subchapter under section 426-1 of this title after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before August 5, 1997, (with respect to periods beginning on or after February 1, 1990, this subparagraph shall be applied by substituting “18-month” for “12-month” each place it appears. Effective for items and services furnished on or after August 5, 1997, (with respect to periods beginning on or after the date that is 18 months prior to August 5, 1997), clauses (i) and (ii) shall be applied by substituting “30-month” for “12-month” each place it appears.

(D) Treatment of certain members of religious orders

In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) General provisions

For purposes of this subsection:

8So in original. The comma probably should not appear.
(i) Aggregation rules

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of such Code) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of such Code) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(m) of such Code.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) “Current employment status” defined

An individual has “current employment status” with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) Treatment of self-employed persons as employers

The term “employer” includes a self-employed person.

(F) Limitation on beneficiary liability

An individual who is entitled to benefits under this subchapter and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer

(A) In general

Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workman’s compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term “primary plan” means a group health plan or large group health plan, to the extent that clause (i) applies, and a workman’s compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) Conditional payment

(i) Authority to make conditional payment

The Secretary may make payment under this subchapter with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) Repayment required

A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this subchapter with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan’s responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan’s insured, or by other means. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan’s responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations) to the appropriate Trust Fund.

(iii) Action by United States

In order to recover payment made under this subchapter for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A), collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan (including a self-insured plan) that has received payment from a primary plan (including a self-insured plan) that has received payment from a primary plan (including a self-insured plan) that has received payment from a primary plan (including a self-insured plan).
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(3) Enforcement

(A) Private cause of action

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in the case of a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(C) Treatment of questionnaires

The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(v) Waiver of rights

The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this subchapter.

(vi) Claims-filing period

Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible for such basis, and

(C) Prohibition of financial incentives not to enroll

It is unlawful for an employer or other entity to offer any financial or other incentive

for an individual entitled to benefits under this subchapter not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1320a–7(a) of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty proceeding under section 1320a–7(a) of this title.

(4) Coordination of benefits

Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this subchapter (without regard to deductibles and coinsurance under this subchapter) for the remainder of such charge, but—

(A) payment under this subchapter may not exceed an amount which would be payable under this subchapter for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this subchapter, when combined with the amount payable under the primary plan, may not exceed—

(i) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(ii) the reasonable charge or other amount which would be payable under this subchapter (without regard to deductibles and coinsurance under this subchapter), whichever is greater.

(5) Identification of secondary payer situations

(A) Requesting matching information

(i) Commissioner of Social Security

The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of Medicare beneficiaries (as defined in section 6103(k)(12) of the Internal Revenue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) Administrator

The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Ad-
ministration to disclose to the Administrator the information described in subparagraph (B) of section 6103(l)(12) of the Internal Revenue Code of 1986.

(B) Disclosure to fiscal intermediaries and carriers
In addition to any other information provided under this subchapter to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers
(i) In general
With respect to each individual (in this subparagraph referred to as an “employee”) who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section 6103(l)(12)(E)(ii) of such Code), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee’s spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) Employer response
Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Obtaining information from beneficiaries
Before an individual applies for benefits under part A of this subchapter or enrolls under part B of this subchapter, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(6) Screening requirements for providers and suppliers
(A) In general
Notwithstanding any other provision of this subchapter, no payment may be made for any item or service furnished under part B of this subchapter unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) Penalties
An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(7) Required submission of information by group health plans
(A) Requirement
On and after the first day of the first calendar quarter beginning after the date that is 1 year after December 29, 2007, an entity serving as an insurer or third party administrator for a group health plan, as defined in paragraph (1)(A)(v), and, in the case of a group health plan that is self-insured and self-administered, a plan administrator or fiduciary, shall—

(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been a primary plan to the program under this subchapter; and

(ii) submit such information to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Enforcement
(i) In general
An entity, a plan administrator, or a fiduciary described in subparagraph (A) that fails to comply with the requirements under such subparagraph shall be subject to a civil money penalty of $1,000 for each day of noncompliance for each individual for which the information under such subparagraph should have been submitted. The provisions of subsections (e) and (k) of section 1320a-7a of this title shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this subchapter with respect to an individual.

(ii) Deposit of amounts collected
Any amounts collected pursuant to clause (i) shall be deposited in the Federal...
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Hospital Insurance Trust Fund under section 1395i of this title.

(C) Sharing of information

Notwithstanding any other provision of law, under terms and conditions established by the Secretary, the Secretary—

(i) shall share information on entitlement under part A and enrollment under part B under this subchapter with entities, plan administrators, and fiduciaries described in subparagraph (A);

(ii) may share the entitlement and enrollment information described in clause (i) with entities and persons not described in such clause; and

(iii) may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(D) Implementation

Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(8) Required submission of information by or on behalf of liability insurance (including self-insurance), no fault insurance, and workers' compensation laws and plans

(A) Requirement

On and after the first day of the first calendar quarter beginning after the date that is 18 months after December 29, 2007, an applicable plan shall—

(i) determine whether a claimant (including an individual whose claim is unresolved) is entitled to benefits under the program under this subchapter on any basis; and

(ii) if the claimant is determined to be so entitled, submit the information described in subparagraph (B) with respect to the claimant to the Secretary in a form and manner (including frequency) specified by the Secretary.

(B) Required information

The information described in this subparagraph is—

(i) the identity of the claimant for which the determination under subparagraph (A) was made; and

(ii) such other information as the Secretary shall specify in order to enable the Secretary to make an appropriate determination concerning coordination of benefits, including any applicable recovery claim.

(C) Timing

Information shall be submitted under subparagraph (A)(ii) within a time specified by the Secretary after the claim is resolved through a settlement, judgment, award, or other payment (regardless of whether or not there is a determination or admission of liability).

(D) Claimant

For purposes of subparagraph (A), the term "claimant" includes—

(i) an individual filing a claim directly against the applicable plan; and

(ii) an individual filing a claim against an individual or entity insured or covered by the applicable plan.

(E) Enforcement

(i) In general

An applicable plan that fails to comply with the requirements under subparagraph (A) with respect to any claimant shall be subject to a civil money penalty of $1,000 for each day of noncompliance with respect to each claimant. The provisions of subsections (e) and (k) of section 1320a–7a of this title shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title. A civil money penalty under this clause shall be in addition to any other penalties prescribed by law and in addition to any Medicare secondary payer claim under this subchapter with respect to an individual.

(ii) Deposit of amounts collected

Any amounts collected pursuant to clause (i) shall be deposited in the Federal Hospital Insurance Trust Fund.

(F) Applicable plan

In this paragraph, the term "applicable plan" means the following laws, plans, or other arrangements, including the fiduciary or administrator for such law, plan, or arrangement:

(i) Liability insurance (including self-insurance).

(ii) No fault insurance.

(iii) Workers' compensation laws or plans.

(G) Sharing of information

The Secretary may share information collected under this paragraph as necessary for purposes of the proper coordination of benefits.

(H) Implementation

Notwithstanding any other provision of law, the Secretary may implement this paragraph by program instruction or otherwise.

(c) Drug products

No payment may be made under part B of this subchapter for any expenses incurred for—

(1) a drug product—

(A) which is described in section 107(c)(3) of the Drug Amendments of 1962,

(B) which may be dispensed only upon prescription,

(C) for which the Secretary has issued a notice of an opportunity for a hearing under subsection (e) of section 355 of title 21 on a proposed order of the Secretary to withdraw approval of an application for such drug product under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling, and
(D) for which the Secretary has not determined there is a compelling justification for its medical need; and

(2) any other drug product—

(A) which is identical, related, or similar (as determined in accordance with section 310.6 of title 21 of the Code of Federal Regulations) to a drug product described in paragraph (1), and

(B) for which the Secretary has not determined there is a compelling justification for its medical need,

until such time as the Secretary withdraws such proposed order.

(d) Items or services provided for emergency medical conditions

For purposes of subsection (a)(1)(A) of this section, in the case of any item or service that is required to be provided pursuant to section 1395dd of this title to an individual who is entitled to benefits under this subchapter, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient’s presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient’s principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(e) Item or service by excluded individual or entity or at direction of excluded physician; limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities

(1) No payment may be made under this subchapter with respect to any item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) by an individual or entity during the period when such individual or entity is excluded pursuant to section 1320a-7, 1320a-7a, 1320c-5 or 1395u(j)(2) of this title from participation in the program under this subchapter; or

(B) at the medical direction or on the prescription of a physician during the period when he is excluded pursuant to section 1320a-7, 1320a-7a, 1320c-5 or 1395u(j)(2) of this title from participation in the program under this subchapter; or

(2) Where an individual eligible for benefits under this subchapter submits a claim for payment for items or services furnished by an individual or entity excluded from participation in the programs under this subchapter, pursuant to section 1320a-7, 1320a-7a, 1320c-5, 1320c-9 (as in effect on September 2, 1982), 1395u(j)(2), 1395y(d) (as in effect on August 18, 1987), or 1395cc of this title, and such beneficiary did not know or have reason to know that such individual or entity was so excluded, then, to the extent permitted by this subchapter, and notwithstanding such exclusion, payment shall be made for such items or services. In each such case the Secretary shall notify the beneficiary of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to a beneficiary after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the beneficiary of the exclusion of that individual or entity.

(f) Utilization guidelines for provision of home health services

The Secretary shall establish utilization guidelines for the determination of whether or not payment may be made, consistent with paragraph (1)(A) of subsection (a) of this section, under part A or part B of this subchapter for expenses incurred with respect to the provision of home health services, and shall provide for the implementation of such guidelines through a process of selective postpayment coverage review by intermediaries or otherwise.

(g) Contracts with utilization and quality control peer review organizations

The Secretary shall, in making the determinations under paragraphs (1) and (9) of subsection (a) of this section, and for the purposes of promoting the effective, efficient, and economical delivery of health care services, and of promoting the quality of services of the type for which payment may be made under this subchapter, enter into contracts with utilization and quality control peer review organizations pursuant to part B of subchapter XI of this chapter.

(h) Waiver of electronic form requirement

(1) The Secretary—

(A) shall waive the application of subsection (a)(22) of this section in cases in which—

(i) there is no method available for the submission of claims in an electronic form; or

(ii) the entity submitting the claim is a small provider of services or supplier; and

(B) may waive the application of such subsection in such unusual cases as the Secretary finds appropriate.

(2) For purposes of this subsection, the term “small provider of services or supplier” means—

(A) a provider of services with fewer than 25 full-time equivalent employees; or

(B) a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

(i) Awards and contracts for original research and experimentation of new and existing medical procedures; conditions

In order to supplement the activities of the Medicare Payment Advisory Commission under section 1395ww(e) of this title in assessing the safety, efficacy, and cost-effectiveness of new and existing medical procedures, the Secretary may carry out, or award grants or contracts for, original research and experimentation of the
type described in clause (ii) of section 1395ww(e)(6)(E) of this title with respect to such a procedure if the Secretary finds that—

(1) such procedure is not of sufficient commercial value to justify research and experimentation by a commercial organization;

(2) research and experimentation with respect to such procedure is not of a type that may appropriately be carried out by an institute, division, or bureau of the National Institutes of Health; and

(3) such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition.

(j) Nonvoting members and experts

(1) Any advisory committee appointed to advise the Secretary on matters relating to the interpretation, application, or implementation of subsection (a)(1) of this section shall assure the full participation of a nonvoting member in the deliberations of the advisory committee, and shall provide such nonvoting member access to all information and data made available to voting members of the advisory committee, other than information that—

(A) is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section (relating to trade secrets); or

(B) the Secretary determines would present a conflict of interest relating to such nonvoting member.

(2) If an advisory committee described in paragraph (1) organizes into panels of experts according to types of items or services considered by the advisory committee, any such panel of experts may report any recommendation with respect to such items or services directly to the Secretary without the prior approval of the advisory committee or an executive committee thereof.

(k) Dental benefits under group health plans

(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v) 4 of this section) providing supplemental or secondary coverage to individuals also entitled to services under this subchapter shall not require a Medicare claims determination under this subchapter for dental benefits specifically excluded under subsection (a)(12) of this section as a condition of making a claims determination for such benefits under the group health plan.

(2) A group health plan may require a claims determination under this subchapter in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this subchapter pursuant to actions taken by the Secretary.

(l) National and local coverage determination process

(1) Factors and evidence used in making national coverage determinations

The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 371(h) of title 21.

(2) Timeframe for decisions on requests for national coverage determinations

In the case of a request for a national coverage determination that—

(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or

(B) requires such an assessment or deliberation and in which a clinical trial is not requested, the decision on the request shall be made not later than 9 months after the date of the request.

(3) Process for public comment in national coverage determinations

(A) Period for proposed decision

Not later than the end of the 6-month period (or 9-month period for requests described in paragraph (2)(B)) that begins on the date a request for a national coverage determination is made, the Secretary shall make a draft of proposed decision on the request available to the public through the Medicare & Medicaid Services or other appropriate means.

(B) 30-day period for public comment

Beginning on the date the Secretary makes a draft of the proposed decision available under subparagraph (A), the Secretary shall provide a 30-day period for public comment on such draft.

(C) 60-day period for final decision

Not later than 60 days after the conclusion of the 30-day period referred to under subparagraph (B), the Secretary shall—

(i) make a final decision on the request; (ii) include in such final decision summaries of the public comments received and responses to such comments; (iii) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

(iv) in the case of a final decision under clause (i) to grant the request for the national coverage determination, the Secretary shall assign a temporary or permanent code (whether existing or unclassified) and implement the coding change.

(4) Consultation with outside experts in certain national coverage determinations

With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

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4So in original. Probably should be “(a)(1)(A)(v)”. 

(5) Local coverage determination process

(A) Plan to promote consistency of coverage determinations

The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

(B) Consultation

The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on all new local coverage determinations within the area.

(C) Dissemination of information

The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

(6) National and local coverage determination defined

For purposes of this subsection—

(A) National coverage determination

The term “national coverage determination” means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter.

(B) Local coverage determination

The term “local coverage determination” has the meaning given in section 1395ff(f)(2)(B) of this title.

(m) Coverage of routine costs associated with certain clinical trials of category A devices

(1) In general

In the case of an individual entitled to benefits under part A of this subchapter, or enrolled under part B of this subchapter, or both who participates in a category A clinical trial, the Secretary shall not exclude under subsection (a)(1) of this section payment for coverage of routine costs of care (as defined by the Secretary) furnished to such individual in the trial.

(2) Category A clinical trial

For purposes of paragraph (1), a “category A clinical trial” means a trial of a medical device if—

(A) the trial is of an experimental/investigational (category A) medical device (as defined in regulations under section 1395x(o)(7)(C) of this title).

(n) Requirement of a surety bond for certain providers of services and suppliers

(1) In general

The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

(2) Provider of services or supplier described

A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1395m(a)(16)(B) and 1395x(o)(7)(C) of this title.

(o) Suspension of payments pending investigation of credible allegations of fraud

(1) In general

The Secretary may suspend payments to a provider of services or supplier under this subchapter pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

(2) Consultation

The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

(3) Promulgation of regulations

The Secretary shall promulgate regulations to carry out this subsection and section 1396b(i)(2)(C) of this title.

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


CODIFICATION

Section 1314(i) of this title, which was transferred and redesignated as subsec. (j) of this section by Pub. L. 108–173, was based on act Aug. 14, 1965, ch. 531, title XI, §1114(i), as added Pub. L. 106–554, §1(a)(6) [title V, §522(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–546.

Amendments by section 301(a) to (c) of Pub. L. 108–173 were executed to this section as it read on the date of enactment of Pub. L. 108–173 to reflect the probable intent of Congress, notwithstanding section 301(d) of Pub. L. 108–173, set out as an Effective Date of 2003 Amendment note below, which provided that the amendments by section 301(a) of Pub. L. 108–173 be effective as if included in the enactment of title III of Pub. L. 98–369 and that the amendments by section 301(b), (c) of Pub. L. 108–173 be effective as if included in the enactment of section 953 of Pub. L. 96–499. The amendments by section 301(a) are incapable of being executed to this section as it read on the effective date of title III of Pub. L. 98–369, and the amendments by section 301(b), (c) are incapable of being executed to this section as it read on the effective date of section 953 of Pub. L. 96–499. See 2003 Amendment notes below.

AMENDMENTS


2008—Subsec. (a)(1)(A). Pub. L. 110–275, §101(a)(3), inserted “or additional preventive services” (as described in section 1395x(a)(1)(A) of this title) after “succeeding subparagraph”.

Subsec. (a)(1)(K). Pub. L. 110–275, §101(b)(3), (4), substituted “more” for “not later” and “1 year” for “6 months”.


Subsec. (a)(20). Pub. L. 110–275, §143(b)(7), substituted “outpatient physical therapy services, outpatient speech-language pathology services, or outpatient occupational therapy services” for “outpatient occupational therapy services and outpatient physical therapy services” and “subsection (g) or (l)” of section 1395x of this title for “subsection (g)”.


same conditions as any employee, and the spouse of such employee, under age 65.”
Subsec. (b)(1)(A). Pub. L. 103–66, §13561(e)(1)(B), substituted “unless the plan is a plan of, or contributed to by, an employer or employee organization that has 20 or more employees” for “unless the plan is sponsored by or contributed to by an employer that has 20 or more employees.”
Subsec. (b)(1)(A)(iii). Pub. L. 103–66, §13561(c)(1)(C), substituted “by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status” for “by virtue of employment with an employer that does not have 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year and for “by virtue of employment with an employer or employee organization that has 20 or more individuals in current employment status with an employer that does not have 20 or more individuals in current employment status” for “by virtue of employment with an employer or employee organization that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year.”
Subsec. (b)(1)(A)(iv). Pub. L. 103–66, §13561(c)(2), substituted “Subparagraph (C) shall apply instead of clause (i)” for “Clause (i) shall not apply and inserted ‘(without regard to entitlement under section 426 of this title)’ after ‘individual is, or’.”
Subsec. (b)(1)(B)(i). Pub. L. 103–66, §13561(e)(1)(F), substituted “individuals” for “active individuals” in clause (iv) and inserted “(without regard to entitlement under section 426 of this title)” after “individual is, or”.
Subsec. (b)(1)(B)(ii). Pub. L. 103–66, §13561(c)(2), substituted “Subparagraph (C) shall apply instead of clause (i)” for “Clause (i) shall not apply” and inserted “(without regard to entitlement under section 426 of this title)” after “individual is, or”.
Subsec. (b)(1)(C). Pub. L. 103–66, §13561(c)(1), (3), substituted “or eligible for benefits under this subchapter under “benefits under this subchapter solely because of” in cl. (i) and concluding provisions and substituted “before October 1, 1998” for “on or before January 1, 1996” in concluding provisions.
Subsec. (b)(5)(B). Pub. L. 103–66, §13561(b)(1)(A), substituted “or under—” for “for the purposes of carrying out this subsection,” and added cls. (i) and (ii) and concluding provisions.
Subsec. (b)(5)(C)(i). Pub. L. 103–66, §13561(b)(1)(B), substituted “paragraph (B)” for “paragraph (B)”.
Subsec. (a)(1)(A). Pub. L. 101–508, §4163(d)(2)(A)(ii), substituted “a succeeding subparagraph for “subparagraph (B), (C), (D), or (E)”.
Subsec. (a)(3). Pub. L. 101–508, §4163(a)(3)(C)(i), inserted “in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, after “section 1395x(aa)(1) of this title,”.
Subsec. (a)(7). Pub. L. 101–508, §4163(d)(2)(B), inserted “or under paragraph (1)(F)” after “paragraph (1)(B)”.
Pub. L. 101–508, §4153(b)(2)(B), inserted “(other than eyewear described in section 1395y(8) of this title)” after first reference to “eyeglasses”.
Subsec. (a)(14). Pub. L. 101–508, §4153(c)(1), inserted “services described by section 1395x(x)(2)/(K)(i) or (ii) (as defined in section 1395x(x)(8) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist,” after “this paragraph)” and struck out before semicolon at end “or are services of a certified registered nurse anesthetist”.
Subsec. (a)(15). Pub. L. 101–508, §4107(b), designated existing provisions as par. (A), substituted “,” or “ for “; or” at end, and added par. (B).
Subsec. (b)(1)(C). Pub. L. 101–508, §4203(c)(1)(B), inserted at end “Effective for items and services furnished on or after February 1, 1991, and on or before January 1, 1996, (with respect to periods beginning on or after February 1, 1990), clauses (i) and (ii) shall be applied by substituting ‘18-month’ for ‘12-month’ each place it appears.”
Subsec. (b)(1)(C)(i). Pub. L. 101–508, §4303(c)(1)(A), substituted “during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A of this subchapter under the provisions of section 426–1 of this title or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 426–1 of this title if the individual had filed an application for such benefits; and” for “during the 12-month period which begins with the earlier of—clause (i) the month in which a regular course of renal dialysis is initiated, or “(ii) the case of an individual who receives a kidney transplant, the first month in which in which he would be eligible for benefits under part A of this subchapter (if he had filed an application for such benefits) under the provisions of section 426–1(b)(1)(B) of this title, and”.
Subsec. (a)(1)(A). Pub. L. 101–234 repealed Pub. L. 100–369, §294(d)(2)(A)(ii), 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 notes below.
Subsec. (a)(1)(F). Pub. L. 101–239, §6115(b), inserted before semicolon at end “, and, in the case of screening pap smear, which is performed more frequently than is provided under 1395x(xmn) of this title”. Pub. L. 101–234 repealed Pub. L. 100–369, §294(d)(2)(A)(ii)–(iv), 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 notes below.
Subsec. (a)(1)(G), (6). Pub. L. 101–234 repealed Pub. L. 100–369, §§294(d)(2)(A)(ii)–(iv), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 Amendment notes below.
Subsec. (b). Pub. L. 101–239, §6202(b)(1)(B), amended heading and text generally, substituting par. (1) to (4) relating to Medicare as secondary payer for former par. (1) to (3) relating to items or services paid under workmen’s compensation laws and end stage renal disease program.

Subsec. (c). Pub. L. 101–239 repealed Pub. L. 100–360, §1902(d), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (h)(1). Pub. L. 101–239, §611(d)(2), inserted “, not including items or services furnished in an emergency room of a hospital” after “in an emergency item or service”.

Subsec. (a)(1)(A). Pub. L. 100–360, §204(d)(2)(A)(i), substituted “a succeeding subparagraph” for “subparagraph (B), (C), (D), or (E)”.


Subsec. (a)(6). Pub. L. 100–360, §205(e)(1)(B), inserted “and except, in the case of in-home care, as is otherwise permitted under paragraph (1)(C)” after “paragraph (1)(C)”.

Subsec. (a)(7). Pub. L. 100–360, §204(d)(2)(B), inserted “or under paragraph (1)(F)” after “(1)(B)”.


Subsec. (c). Pub. L. 100–360, §202(d), designated existing provisions as par. (1), redesignated former par. (1) as subpar. (A), redesignated former subpars. (A) to (D) as cls. (i) to (iv), redesignated former par. (2) as subpar. (B), redesignated former subpar. (A) as cl. (i) and substituted “(or to the spouse of such individual)” for “(or to the spouse of such individual)”. Pub. L. 100–360, §204(d)(2)(B), inserted “(including subsequent insertion of an intraocular lens)” after “operation”.

Subsec. (e)(1). Pub. L. 100–360, §411(d)(4)(D)(ii), as amended by Pub. L. 100–485, §608(d)(2)(C)(ii), redesignated former section 1395aaa of this title by striking out the catchline “Limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities”, substituting “(2)” for “(2)” for the section designation, inserting “1395u(j)(2)”, in text, and transferring the text to par. (2) of subsection (e) of this section.

1987—Subsec. (a)(1)(A). Pub. L. 100–203, §4085(c)(15), substituted “(D) or (E)” for “or (D)”.

Subsec. (a)(1)(C). Pub. L. 100–203, §4072(c), inserted “other than shoes furnished pursuant to section 1395l(s)(12) of this title” before semicolon.

Subsec. (a)(14). Pub. L. 100–203, §4085(c)(16), substituted “a patient” for “an patient”.


Subsec. (b)(2)(A)(ii). Pub. L. 100–203, §4086(a)(1), substituted “can reasonably be expected to be made under such a plan” for “the Secretary determines will be made under such a plan as promptly as would otherwise be the case if payment were made by the Secretary under this subchapter”.

Subsec. (b)(4)(B)(i). Pub. L. 100–203, §4043(a), substituted subsection (b) of section 5000 of the Internal Revenue Code of 1986 without regard to subsection (d) of such section for “section 5000(b) of the Internal Revenue Code of 1986”.

Subsec. (d). Pub. L. 100–93, §8(c)(1)(A), struck out subsec. (d) which provided that no payment be made under this subchapter for any item or services to an individual by a person where Secretary determines such person knowingly and willfully made any false statement or representation of a material fact, submitted excessive bills or requests, or furnished excessive services or supplies, and provided a dissatisfied person with a hearing on determination of the Secretary.


Pub. L. 100–93, §8(c)(1)(B), amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: “No payment may be made under this subchapter with respect to any item or service furnished by a physician or other individual during the period when he is barred pursuant to section 1320a–7 of this title from participation in the program under this subchapter.”

Subsec. (h)(1)(B). Pub. L. 100–203, §4039(c)(1)(B), inserted “in determining the amount subject to repayment under paragraph (2)(C)” after “(3)”.


Subsec. (h)(4). Pub. L. 100–93, §8(c)(3), substituted “subsections (c), (f), and (g) of section 1320a–7a of this title” for “(paragraphs 2 and 3 of subsection (d) of this section)”.

Subsec. (h)(4)(B). Pub. L. 100–203, §4039(c)(1)(D), substituted “, has improperly” for “or has improperly” and inserted “or has failed to make repayment to the Secretary as required under paragraph 2(C)” after “2(B)”.


Pub. L. 99–509, §9320(h)(1), as amended by Pub. L. 100–203, §4009(b)(6)(C), inserted “or any services of a certified registered nurse anesthetist” after “hospital” at end.


Subsec. (b)(3)(A)(i). Pub. L. 99–272, §9201(a)(1), substituted “(or to the spouse of such individual)” for “(or to the spouse of such individual)”.

Subsec. (b)(6). Pub. L. 99–272, §9201(a)(2), struck out “and ending with the month before the month in which such individual attains the age of 70” after “section 426(a) of this title”.


Subsec. (b)(11). Pub. L. 98–369, §2944(a), substituted “to be made promptly” for “to be made” and “has been or could be made under such a law” for “has been made under such a law”, and inserted “In order to recover payment made under this subchapter for an item or service, the United States may bring an action against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a law, policy, plan, or insurance, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such law, policy, plan, or insurance, and may join or intervene in any action related to the events that gave rise to the need for such item or service.”
Subsec. (b)(2)(B). Pub. L. 98–369, §2344(b), substituted “has been or could be made under a plan” for “has been made under a plan”, and inserted “in order to recover payment made under this subchapter for an item or service, the United States may bring an action against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a plan, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such plan, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated (to the extent of payment made under this subchapter for an item or service) to any right of an individual or any other entity to payment with respect to such item or service under such a plan.”

Subsec. (b)(3)(A)(i). Pub. L. 98–369, §2301(a), struck out “over 64 but” before “under 70 years” in two places.


Subsec. (b). Pub. L. 96–499, §953, inserted “or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance” and “or a State” and “policy, plan, or insurance” after “or a” and clinical status”. Subsec. (a)(13)(C).


Subsec. (e). Pub. L. 96–499, §913(b), substituted provisions barring payment under this subchapter with respect to items or services furnished by a physician or other individual during a period when such physician or other individual was barred pursuant to section 1320a–7 of this title from participation under any health benefit plan, or against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a plan, or under no fault insurance, or a State or the United States may bring an action against any entity which would be responsible for payment with respect to such item or service (or any portion thereof) under such a plan, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such plan, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated (to the extent of payment made under this subchapter for an item or service) to any right of an individual or any other entity to payment with respect to such item or service under such a plan.”

Subsec. (b)(3)(A)(i). Pub. L. 98–369, §2301(c), added subsec. (b)(3). Pub. L. 97–248, §122(f)(4), inserted “except in the case of rural health clinic services, as defined in section 1395x(aa)(1) of this title, and in such other cases as the Secretary may specify” for “except in such cases as the Secretary may specify”.

Subsec. (d)(1)(B). Pub. L. 95–142, §13(b)(1), struck out requirement for concurrence of appropriate program review team for finding of Secretary under this paragraph.

Subsec. (d)(1)(C). Pub. L. 95–142, §13(b)(2), substituted provisions relating to determinations by the Secretary on the basis of reports transmitted to him in accordance with section 1395x(a)(1) of this title and section 1320c–6 of this title or other data acquired in the administration of this subchapter, for provisions relating to determinations by the Secretary with the concurrence of appropriate review team members.

Subsec. (d)(4). Pub. L. 95–142, §13(a), struck out par. (4) which set forth provisions relating to appointment and functions of program review teams.


Subsec. (c). Pub. L. 95–142 struck out subsec. (c) prohibiting payments to Federal employees under this subchapter unless a determination and certification by the Secretary of a modification of any health benefit plan under chapter 95 of Title 5 was made which would allow a Federal employee benefits under part A or B of this plan.


Subsec. (c)(12). Pub. L. 93–233, added subsec. (c)(12). Pub. L. 93–233 substituted “the provision of such dental services if the individual, be responsible for payment with respect to such item or service (or any portion thereof) under such a plan, or against any entity (including any physician or provider) which has been paid with respect to such item or service under such plan, and may join or intervene in any action related to the events that gave rise to the need for such item or service. The United States shall be subrogated (to the extent of payment made under this subchapter for an item or service) to any right of an individual or any other entity to payment with respect to such item or service under such a plan.,”.
where the individual suffers from impairments of such severity as to require hospitalization".

1972—Subsec. (a)(4). Pub. L. 92-603, § 211(c)(1), inserted reference to physicians' services and ambulance services furnished an individual in conjunction with emergency inpatient hospital services.

Subsec. (a)(12). Pub. L. 92-603, § 256(c), authorized payment for procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.


Subsec. (c). Pub. L. 92-603, § 210, added subsec. (c).


1966—Subsec. (a)(7). Pub. L. 90-248, § 128, prohibited payment for procedures performed (during the course of any eye examination) to determine the refractive state of the eyes.


 EFFECTIVE DATE OF 2010 AMENDMENT
Amendment by section 4103(d) of Pub. L. 111-148 applicable to services furnished on or after Jan. 1, 2011, see section 4103(e) of Pub. L. 111-148, set out as a note under section 1395l of this title.

 EFFECTIVE DATE OF 2008 AMENDMENT
Amendment by section 101(a)(3), (b)(5), (4) of Pub. L. 110-275 applicable to services furnished on or after Jan. 1, 2009, see section 101(c) of Pub. L. 110-275, set out as a note under section 1395l of this title.

Pub. L. 110-275, title I, § 135(a)(2)(B), July 15, 2008, 122 Stat. 2535, provided that: "The amendments made by this paragraph (amending this section) shall apply to claims submitted on or after October 16, 2008,

 EFFECTIVE DATE OF 2006 AMENDMENT
Amendment by Pub. L. 109-171 applicable to services furnished on or after Jan. 1, 2007, see section 5112(f) of Pub. L. 109-171, set out as a note under section 1395l of this title.

 EFFECTIVE DATE OF 2003 AMENDMENT
Pub. L. 108-173, title III, § 301(d), Dec. 8, 2003, 117 Stat. 2222, provided that: "The amendments made by this section [amending this section] shall be effective—

“(1) in the case of subsection (a), as if included in the enactment of title III [sic] of the Medicare and Medicaid Budget Reconciliation Amendments of 1997 (Public Law 98-369); and

“(2) in the case of subsections (b) and (c), as if included in the enactment of section 953 of the Omnibus Reconciliation Act of 1989 (Public Law 96-496; 94 Stat. 2647)."

Amendment by section 611(d)(1) of Pub. L. 108-173 applicable to services furnished on or after Jan. 1, 2005, but only for individuals whose coverage period under this part begins on or after such date, see section 611(e) of Pub. L. 108-173, set out as a note under section 1395w-4 of this title.

Amendment by section 612(c) of Pub. L. 108-173 applicable to tests furnished on or after Jan. 1, 2005, see section 612(d) of Pub. L. 108-173, set out as a note under section 1395x of this title.

Amendment by section 613(c) of Pub. L. 108-173 applicable to tests furnished on or after Jan. 1, 2005, see section 613(d) of Pub. L. 108-173, set out as a note under section 1395x of this title.

Pub. L. 108-173, title VII, § 731(a)(2), Dec. 8, 2003, 117 Stat. 2351, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to national coverage determinations as of January 1, 2004, and section 1862(l)(5) of the Social Security Act [subsec. (l)(5) of this section], as added by such paragraph, shall apply to local coverage determinations made on or after July 1, 2004."

Pub. L. 108-173, title VII, § 731(b)(2), Dec. 8, 2003, 117 Stat. 2351, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to routine costs incurred on and after January 1, 2005, and, as of such date, section 411.150 of title 42, Code of Federal Regulations, is superseded to the extent inconsistent with section 1902(m) of the Social Security Act [subsec. (m) of this section], as added by such paragraph."


Amendment by section 948(a) of Pub. L. 108-173 effective, except as otherwise provided, as if included in the enactment of HIPAA [the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, H.R. 5661, as enacted by section 1(a)(6) of Public Law 106-554], see section 948(e) of Pub. L. 108-173, set out as a note under section 1314 of this title.

Pub. L. 108-173, title IX, § 950(b), Dec. 8, 2003, 117 Stat. 2427, provided that: "The amendment made by subsection (a) [amending this section] shall take effect on the date that is 60 days after the date of the enactment of this Act [Dec. 8, 2003]."

 EFFECTIVE DATE OF 2001 AMENDMENT
Pub. L. 107-105, § 3(b), Dec. 27, 2001, 115 Stat. 1007, provided that: "The amendments made by subsection (a) [amending this section] shall apply to claims submitted on or after October 16, 2003."

 EFFECTIVE DATE OF 2000 AMENDMENT
Amendment by section 1(a)(6) (title I, § 102(c)) of Pub. L. 106-554 applicable to services furnished on or after Jan. 1, 2002, see section 1(a)(6) (title I, § 102(d)) of Pub. L. 106-554, set out as a note under section 1395u of this title.

Amendment by section 1(a)(6) (title III, § 305(b)) of Pub. L. 106-554 applicable to services furnished on or after Jan. 1, 2001, see section 1(a)(6) (title III, § 313(c)) of Pub. L. 106-554, set out as a note under section 1395u of this title.

Amendment by section 1(a)(6) (title IV, § 422(b)(1)) of Pub. L. 106-554 applicable to services furnished on or after July 1, 2001, see section 1(a)(6) (title IV, § 422(c)) of Pub. L. 106-554, set out as a note under section 1395u of this title.

Amendment by section 1(a)(6) (title V, § 522(b)) of Pub. L. 106-554 applicable with respect to a review of any national or local coverage determination filed, a request to make such a determination made, and a national coverage determination made, on or after Oct. 1, 2001, see section 1(a)(6) (title V, § 522(d)) of Pub. L. 106-554, set out as a note under section 1314 of this title.

 EFFECTIVE DATE OF 1999 AMENDMENT
Amendment by section 1000(a)(6) (title III, § 305(b)) of Pub. L. 106-113 applicable to payments for services provided on or after Nov. 29, 1999, see § 1000(a)(6) (title III, § 305(c)) of Pub. L. 106-113, set out as a note under section 1395u of this title.


 EFFECTIVE DATE OF 1997 AMENDMENTS
Amendment by Pub. L. 105-12 effective Apr. 30, 1997, and applicable to Federal payments made pursuant to obligations incurred after Apr. 30, 1997, for items and services furnished on or after Jan. 1, 2005, see section 1395x of this title.
services provided on or after such date, subject to also being applicable with respect to contracts entered into, renewed, or extended after Apr. 30, 1997, as well as contracts entered into before April 1, 1997, to the extent permitted under such contracts, see section 11 of Pub. L. 105–12, set out as an Effective Date note under section 14401 of this title.

Amendment by section 4022(b)(1)(B) of Pub. L. 105–33 effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission and the Physician Payment Review Commission, see section 4022(c)(2) of Pub. L. 105–33, set out as an Effective Date: Transition; Transfer of Functions note under section 1395(b)–6 of this title.

Amendment by section 4102(c) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4102(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4103(c) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 2000, see section 4103(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4104(c)(3) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4201(d) 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.

Amendment by section 4320(b)(1) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1998, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395i–3 of this title.

Amendment by section 4507(a)(1)(B) of Pub. L. 105–33 applicable with respect to contracts entered into on and after Jan. 1, 1998, see section 4507(c) of Pub. L. 105–33, set out as a note under section 1395i of this title.

Amendment by section 4541(b) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1998, including portions of cost reporting periods occurring on or after such date, see section 4541(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4603(c)(2)(C) of Pub. L. 105–33 applicable to cost reporting periods beginning on or after Oct. 1, 1999, except as otherwise provided, see section 4603(d) of Pub. L. 105–33, set out as an Effective Date note under section 1395ff of this title.

Amendment by section 4610(c) of Pub. L. 105–33 provided that: "The amendments made by this section (amending this section) apply to services furnished on or after October 1, 1997.

Section 4632(b) of Pub. L. 105–33 provided that: "The amendments made by this section (amending this section) apply to items and services furnished on or after the date of the enactment of this Act [Aug. 5, 1997]."

SECTION 151(b)(3)(C) OF PUB. L. 103–432 Provided that: "The amendments made by this paragraph [amending this section] shall apply to payments for items and services furnished on or after the date of the enactment of this Act [Oct. 31, 1994]."

Section 151(c)(1), (9) of Pub. L. 103–432 provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–432.

Section 151(c)(4) of Pub. L. 103–432 provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–432.

Section 151(c)(5), (6) of Pub. L. 103–432 provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–432.

Section 155(a)(2)(D) of Pub. L. 103–432 applicable to services provided on or after Oct. 31, 1994, see section 155(a)(3) of Pub. L. 103–432, set out as a note under section 1320c–3 of this title.

Section 157(b)(8) of Pub. L. 103–432 provided that: "The amendments made by this subsection [amending this section, section 1395sm of this title, and provisions set out as notes under section 1395sm of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–568]."

EFFECTIVE DATE OF 1993 AMENDMENT

Section 151(c)(10) of Pub. L. 103–432 provided that: "The amendment made by section 15361(i)(1)(G) of OBRA–1993 [Pub. L. 103–66, amending this section], to the extent it relates to the definition of large group health plan, shall be effective as if included in the enactment of OBRA–1989 [Pub. L. 101–239]."


Section 15381(d) of Pub. L. 103–66 provided that: "The amendments made by this section [enacting section 1320c–14 and amending this section, section 1396a of this title, and section 552a of Title 5, Government Organization and Employees] shall take effect on January 1, 1994."

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 4153(b)(2)(C) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1991, see section 4153(b)(2)(C) of Pub. L. 101–508, set out as a note under section 1396x of this title.

Amendment by section 4157(d) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4157(d) of Pub. L. 101–508, set out as a note under section 1396x of this title.

Amendment by section 4161(a)(3)(C) of Pub. L. 101–508 applicable to services furnished on or after Oct. 1, 1991, see section 4161(a)(3)(C) of Pub. L. 101–508, set out as a note under section 1396x of this title.

Amendment by section 4163(d)(2)(A)(i)–(iii), (B) 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, as amended, set out as a note under section 1385f of this title.


Section 4204(g)(2) of Pub. L. 101–508 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to incentives offered on or after the date of the enactment of this Act [Nov. 5, 1990]."
Effective Date of 1989 Amendments

Amendment by section 6115(b) of Pub. L. 101–239 applicable to screening pap smears performed on or after July 1, 1990, see section 6115(d) of Pub. L. 101–239, set out as a note under section 1395x of this title.

Amendment by section 6202(b)(1) of Pub. L. 101–239 applicable to items and services furnished after Dec. 19, 1989, see section 6202(b)(b) of Pub. L. 101–239, set out as a note under section 162 of Title 26, Internal Revenue Code.

Section 6202(e)(2) of Pub. L. 101–239 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to items and services furnished on or after October 1, 1989."


Effective Date of 1988 Amendments


Amendment by section 202(d) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(m)(1) of Pub. L. 100–360, set out as a note under section 1395u of this title.

Amendment by section 204(d)(2) of Pub. L. 100–360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 205(e)(1) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(f) of Pub. L. 100–360, set out as a note under section 1395k of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(i)(4)(D) of Pub. L. 100–360 shall relate to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a reference to OBRA: Effective Date note under section 106 of Title 1, General Provisions.

Section 411(f)(4)(D)(ii) of Pub. L. 100–360 provided that: "The amendment made by clause (i) [amending this section] shall apply to operations performed on or after 60 days after the date of the enactment of this Act [July 1, 1988]."

Effective Date of 1987 Amendments

Section 4009(j)(6) of Pub. L. 100–203, provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 99–509.

Section 4009(b) of Pub. L. 100–203 provided that: "The amendment made by subsection (a) [amending this section] shall be effective as if included in the enactment of section 911(a) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509]."

Section 4034(b) of Pub. L. 100–203 provided that: "The amendment made by that section is effective as if included as a part of this section as this section was amended by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, see section 309(c)(2) of Pub. L. 97–248, set out as a note under section 1320c–3 of this title.

Effective Date of 1986 Amendments

Section 9318(f) of Pub. L. 99–509 provided that: "(1) Except as provided in paragraph (2), the amendments made by this section [enacting section 5000 of Title 26, Internal Revenue Code, and amending this section and sections 1395p and 1395r of this title] shall apply to items and services furnished on or after January 1, 1987.

"(2) The amendments made by subsection (c) [amending sections 1395p and 1395r of this title] shall apply to enrollments occurring on or after January 1, 1987.

Amendment by section 602(b)(1) 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 602(b)(1), (k) of Pub. L. 99–509, as amended, set out as notes under section 1395k of this title.

Amendment by section 9343(c)(1) of Pub. L. 99–509 applicable to services furnished after June 30, 1987, see section 9343(b)(2) of Pub. L. 99–509, as amended, set out as a note under section 1395k of this title.

Section 9201(d)(1) of Pub. L. 99–272 provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to items and services furnished on or after May 1, 1986.

Amendment by section 9307(a) of Pub. L. 99–272 applicable to services performed on or after Apr. 1, 1986, see section 9307(e) of Pub. L. 99–272, set out as a note under section 1320c–3 of this title.

Effective Date of 1984 Amendment

Section 2301(c)(1) of Pub. L. 98–369 provided that: "The amendment made by subsection (a) [amending this section] shall be effective with respect to items and services furnished on or after January 1, 1985."

Amendment by section 2304(c) of Pub. L. 98–369 applicable to pacemaker devices and leads implanted or removed on or after the effective date of final regulations promulgated to carry out such amendment, see section 2304(d) of Pub. L. 98–369, set out as a note below.

Section 2354(a) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section and section 1395ww of this title] shall become effective on the date of the enactment of this Act [July 18, 1984]."

Section 2354(d) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section] shall apply to items and services furnished on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2354(b)(30), (31) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

Effective Date of 1983 Amendments

Amendment by section 601(f) 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, and amendment by section 602(e)(3) of Pub. L. 98–21 effective Oct. 1, 1983, see section 604(a)(1), (2) of Pub. L. 98–21, set out as a note under section 1320c–3 of this title.

Amendment by Pub. L. 97–448 effective as if originally included as a part of this section as this section was amended by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, see section 309(c)(2) of Pub. L. 97–448, set out as a note under section 1320c–3 of this title.

Effective Date of 1982 Amendment

Amendment by section 116(b) of Pub. L. 97–248 applicable with respect to items and services furnished on or after Jan. 1, 1983, see section 116(c) of Pub. L. 97–248, set out as a note under section 1320a–7 of Title 42, Labor.
1983, see section 122(h)(1) of Pub. L. 97–248, as amended, set out as a note under section 139e(c) of this title.

Amendment by section 128(a)(2)–(4) of Pub. L. 97–248 effective as if originally included as part of this section as this section was amended by the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, see section 128(c)(2) of Pub. L. 97–248, set out as a note under section 139e(c) of this title.

Amendment by sections 142 and 148(a) of Pub. L. 97–248 effective with respect to contracts entered into or renewed on or after Sept. 3, 1982, see section 149 of Pub. L. 97–248, set out as an Effective Date note under section 1320c of this title.

**Effective Date of 1981 Amendment**

Section 210(a)(2) of Pub. L. 97–35 provided that: “The amendment made by paragraph (1) [amending this section] shall apply with respect to expenses incurred on or after October 1, 1981.”

Section 214(c)(1) of Pub. L. 97–35 provided that: “The amendments made by subsection (a) [amending this section] shall become effective on October 1, 1981.”

**Effective Date of 1980 Amendments**

Amendment by Pub. L. 96–611 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96–611, set out as a note under section 139e(f) of this title.

Amendment by section 936(c) 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 139f of this title.

Section 939(b) of Pub. L. 96–499 provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to services furnished on or after July 1, 1981.”

**Effective Date of 1977 Amendments**

Amendment by Pub. L. 95–210 applicable to services rendered on or after first day of third calendar month which begins after Dec. 31, 1977, see section 1(j) of Pub. L. 95–210, set out as a note under section 1395k of this title.

Section 13(c) of Pub. L. 95–142 provided that: “The amendments made by this section [amending this section and sections 1320c–6 and 1399cc of this title] shall take effect on the date of the enactment of this Act [Oct. 25, 1977].”

**Effective Date of 1973 Amendment**

Amendment by Pub. L. 93–233 effective with respect to admissions occurring after Dec. 31, 1972, see section 211(d) of Pub. L. 93–233, set out as a note under section 1395f of this title.

**Effective Date of 1972 Amendment**

Amendment by section 211(c)(1) of Pub. L. 92–603 applicable to services furnished with respect to admissions occurring after Dec. 31, 1972, see section 211(d) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Amendment by section 256(c) 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.

**Effective Date of 1968 Amendment**

Amendment by section 127(b) of Pub. L. 90–248 applicable with respect to services furnished after Dec. 31, 1967, see section 127(c) of Pub. L. 90–248, set out as a note under section 1395f of this title.

**Constitution of 2008 Amendment**


**Construction of 2007 Amendment**

Pub. L. 110–173, title I, §111(b), Dec. 29, 2007, 121 Stat. 2499, provided that: “Nothing in the amendments made by this section [amending this section] shall be construed to limit the authority of the Secretary of Health and Human Services to collect information to carry out Medicare secondary payer provisions under title XVIII of the Social Security Act [this subchapter], including under parts C and D of such title.”

**Construction of 2003 Amendment**

Pub. L. 108–173, title VII, §731(b)(3), Dec. 8, 2003, 117 Stat. 2351, provided that: “Nothing in the amendment made by paragraph (1) [amending this section] shall be construed as applying to, or affecting, coverage or payment for a nonexperimental/investigational (category B) device.”

**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(b) of Pub. L. 108–173, set out as a note under section 1395u of this title.

Notwithstanding section 303(j) of Pub. L. 108–173 (see note above), amendment by section 303 of Pub. L. 108–173 also applicable to payments for drugs or biologicals and drug administration services furnished by physicians in specialties other than the specialties of hematology, hematology/oncology, and medical oncology, see section 304 of Pub. L. 108–173, set out as a note under section 1395u of this title.

**Treatment of Hospitals for Certain Services Under Medicare Secondary Payor (MSP) Provisions**


“(a) In General.—The Secretary [of Health and Human Services] shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act [subsec. (b) of this section] (relating to medicare secondary payer provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory.

“(b) Reference Laboratory Services Described.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A [probably means part A of title XVIII of the Social Security Act which is classified to part B of this subchapter] or enrolled under part B [probably means part B of title XVIII of the Social Security Act which is classified to part B of this subchapter], or both, and the hospital involved and in which the hospital submits a claim only for such test or interpretation.”

**Annual Publication of List of National Coverage Determinations**

Pub. L. 108–173, title IX, §953(b), Dec. 8, 2003, 117 Stat. 2428, provided that: “The Secretary [of Health and Human Services] shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act [this subchapter] in the previous year and information on how to get more information with respect to such determinations.”
NOTIFICATION TO PHYSICIANS OF EXCESSIVE HOME HEALTH VISITS

Section 4614(b) of Pub. L. 105–33 provided that: "The Secretary of Health and Human Services may establish a process for notifying a physician in cases in which the number of home health visits, furnished under title XVIII of the Social Security Act [this subchapter] pursuant to a prescription or certification of the physician, significantly exceeds such threshold (or thresholds) as the Secretary specifies. The Secretary may adjust such threshold to reflect demonstrated differences in the need for home health services among different beneficiaries.

DISTRIBUTION OF QUESTIONNAIRE BY CONTRACTOR

Section 151(a)(1)(B) of Pub. L. 103–432 provided that: "The Secretary of Health and Human Services shall enter into an agreement with an entity not later than 60 days after the date of the enactment of the Social Security Act Amendments of 1994 [Oct. 31, 1994], to distribute the questionnaire described in section 1862(b)(5)(D) of the Social Security Act [subsec. (b)(5)(D) of this section] (as added by subparagraph (A))."

RETROACTIVE EXEMPTION FOR CERTAIN SITUATIONS INVOLVING RELIGIOUS ORDERS

Section 13581(f) of Pub. L. 103–66 provided that: "Section 1862(b)(1)(D) of the Social Security Act [subsec. (b)(1)(D) of this section] applies, with respect to items and services furnished before October 1, 1989, to any claims that the Secretary of Health and Human Services has not identified as subject to the provisions of section 1862(b) of such Act."

GAO STUDY OF EXTENSION OF SECONDARY PAYER PERIOD


DEADLINE FOR FIRST TRANSMITTAL AND REQUEST OF MATCHING INFORMATION

Section 6202(a)(2)(B) of Pub. L. 101–239 provided that: "The Commissioner of Social Security shall first—

"(i) transmit to the Secretary of the Treasury in information under paragraph (5)(A)(i) of section 1862(b) of the Social Security Act [subsec. (b)(5)(A)(i) of this section] (as inserted by subparagraph (A)), and

"(ii) request from the Secretary disclosure of information described in section 6013(h)(12)(A) of the Internal Revenue Code of 1986 [26 U.S.C. 6013(h)(12)(A)], by no later than 14 days after the date of the enactment of this Act [Dec. 19, 1989]."

DESIGNATION OF PEDIATRIC HOSPITALS AS MEETING CERTIFICATION AS HEART TRANSPLANT FACILITY

Section 4009(b) of Pub. L. 100–205 provided that: "For purposes of determining whether a pediatric hospital that performs pediatric heart transplants meets the criteria established by the Secretary of Health and Human Services for facilities in which the heart transplants performed will be considered to meet the requirement of section 1862(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section], the Secretary shall treat such a hospital as meeting such criteria if—

"(1) the hospital's pediatric heart transplant program is operated jointly by the hospital and another facility that meets such criteria,

"(2) the unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria), and

"(3) the hospital demonstrates to the satisfaction of the Secretary that it is able to provide the special-ized facilities, services, and personnel that are required by pediatric heart transplant patients."

APPROVAL OF SURGICAL ASSISTANTS FOR PROCEDURES PERFORMED APRIL 1, 1986, TO DECEMBER 15, 1986

Section 1895(b)(16)(C) of Pub. L. 99–514 provided that: "For purposes of section 1862(a)(15) of the Social Security Act (42 U.S.C. 1395y(a)(15)), added by section 9307(a)(3) of COBRA, and for surgical procedures performed during the period beginning on April 1, 1986, and ending on December 15, 1986, a carrier is deemed to have approved the use of an assistant in a surgical procedure, before the surgery is performed, based on the existence of a complicating medical condition if the carrier determines after the surgery is performed that the use of the assistant in the procedure was appropriate based on the existence of a complicating medical condition before or during the surgery."

EXTENDING WAIVER OF LIABILITY PROVISIONS TO HOSPICE PROGRAMS


"(1) IN GENERAL.—The Secretary of Health and Human Services shall, for purposes of determining whether payments to a hospice program should be denied pursuant to section 1862(a)(1)(C) of the Social Security Act [subsec. (a)(1)(C) of this section], apply (under section 1879(a) of such Act [section 1395ppa of this title]) a presumption of compliance of 2.5 percent (based on the number of days of hospice care billed) in a manner substantially similar to that provided to home health agencies under policies in effect as of July 1, 1985.

"(2) EFFECTIVE DATE.—Paragraph (1) shall apply to hospice care furnished on or after the first day of the first month that begins at least 6 months after the date of the enactment of this Act [Oct. 21, 1986] and before December 31, 1995."

Section 4008(a)(3) of Pub. L. 101–508 provided that: "The amendments made by paragraphs (1) and (2) [amending section 9305(f) of Pub. L. 99–509, set out above, and section 9126(c) of Pub. L. 99–272, set out below] shall take effect on the date of the enactment of this Act [Nov. 5, 1990]."

STUDY OF IMPACT ON DISABLED BENEFICIARIES AND FAMILY OF AMENDMENTS RELATING TO LARGE GROUP HEALTH PLANS AND MEDICAID AS SECONDARY PAYERS

Section 9313(e) of Pub. L. 99–509 directed Comptroller General to study and report to Congress, not later than Mar. 1, 1990, the impact of the amendments made by this section (enacting section 5009 of Title 26, Internal Revenue Code, and amending this section and sections 1395p and 1396 of this title) on access of disabled individuals and members of their family to employment and health insurance, such report to include information relating to number of disabled medicare beneficiaries for whom medicare has become secondary, either through their employment or the employment of a family member, amount of savings to the medicare program achieved annually through this provision, and effect on employment, and employment-based health coverage, of disabled individuals and family members.

RESTATEMENT OF WAIVER OF LIABILITY PRESUMPTION

Section 9126(c) of Pub. L. 99–272, as amended by Pub. L. 100–366, title IV, §426(b), July 1, 1988, 102 Stat. 814; Pub. L. 101–508, title IV, §4008(a)(1), Nov. 5, 1990, 104 Stat. 1388–44, provided that: "The Secretary of Health and Human Services shall, for purposes of determining whether payments to a skilled nursing facility should be denied pursuant to section 1862(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section], apply the same presumption of compliance (5 percent) as in section 1895(b)(16)(C) of COBRA of COBRA, and for surgical procedures performed during the period beginning on April 1, 1986, and ending on December 15, 1986, a carrier is deemed to have approved the use of an assistant in a surgical procedure, before the surgery is performed, based on the existence of a complicating medical condition if the carrier determines after the surgery is performed that the use of the assistant in the procedure was appropriate based on the existence of a complicating medical condition before or during the surgery."

EXTENDING WAIVER OF LIABILITY PROVISIONS TO HOSPICE PROGRAMS

Section 9305(f) of Pub. L. 99–509, as amended by Pub. L. 100–366, title IV, §426(a), July 1, 1988, 102 Stat. 814; Pub. L. 101–508, title IV, §4008(a)(2), Nov. 5, 1990, 104 Stat. 1388–44, provided that: "(1) IN GENERAL.—The Secretary of Health and Human Services shall, for purposes of determining whether payments to a hospice program should be denied pursuant to section 1862(a)(1)(C) of the Social Security Act [subsec. (a)(1)(C) of this section], apply (under section 1879(a) of such Act [section 1395ppa of this title]) a presumption of compliance of 2.5 percent (based on the number of days of hospice care billed) in a manner substantially similar to that provided to home health agencies under policies in effect as of July 1, 1985.

"(2) EFFECTIVE DATE.—Paragraph (1) shall apply to hospice care furnished on or after the first day of the first month that begins at least 6 months after the date of the enactment of this Act [Oct. 21, 1986] and before December 31, 1995."

Section 4008(a)(3) of Pub. L. 101–508 provided that: "The amendments made by paragraphs (1) and (2) [amending section 9305(f) of Pub. L. 99–509, set out above, and section 9126(c) of Pub. L. 99–272, set out below] shall take effect on the date of the enactment of this Act [Nov. 5, 1990]."
first month beginning after the date of the enactment of this Act [Apr. 7, 1986] and ending on December 31, 1995.''

**HOME HEALTH WAIVER OF LIABILITY**

Section 9205 of Pub. L. 99–272, as amended by Pub. L. 100–360, title IV, § 426(d), July 1, 1988, 102 Stat. 814; Pub. L. 103–422, title I, § 1136(b)(1), Oct. 31, 1994, 108 Stat. 4422, provided that: "The Secretary of Health and Human Services shall, for purposes of determining whether payments to a home health agency should be denied pursuant to section 1862(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section], apply a presumption of compliance (2.5 percent) in the same manner as under the regulations in effect as of July 1, 1985. Such presumption shall apply until December 31, 1995.''

{Section 158(b)(2) of Pub. L. 103–422 provided that:}


**RECOMMENDATIONS AND GUIDELINES FOR ELIMINATION OF ASSISTANTS AT SURGERY; REPORT TO CONGRESS**

Section 9307(d) of Pub. L. 99–272 provided that the Secretary of Health and Human Services, after consultation with the Physician Payment Review Commission, develop recommendations and guidelines respecting other surgical procedures for which an assistant at surgery was generally not medically necessary and circumstances under which use of an assistant at surgery was medically appropriate but should be subject to prior approval of an appropriate entity and that the Secretary report to Congress, not later than January 1, 1987, on these recommendations and guidelines.

**PACEMAKER REIMBURSEMENT REVIEW AND REFORM; PROMULGATION OF REGULATIONS; EFFECTIVE DATE OF PACEMAKER REGISTRATION**

Section 2304(d) of Pub. L. 98–369 provided that: "The Secretary of Health and Human Services shall promulgate final regulations to carry out this section and the amendment made by this section [amending this section and enacting provisions set out as a note under section 1395y of this title] prior to January 1, 1985, and the amendment made by subsection (c) [amending this section] shall apply to pacemaker devices and leads implanted on or after the effective date of such regulations."

**PAYMENT FOR DEBRIDEMENT OF MYCOTIC TOENAILS**

Section 2325 of Pub. L. 98–369 provided that: "The Secretary shall provide, pursuant to section 1882(a) of the Social Security Act [subsec. (a) of this section], that payment will not be made under part B of title XVIII of such Act [part B of this subchapter] for a physician’s debridement of mycotic toenails to the extent such debridement is performed for a patient more frequently than once every 60 days, unless the medical necessity for more frequent treatment is documented by the billing physician."

**INTERIM WAIVER IN CERTAIN CASES OF BILLING RULE FOR ITEMS AND SERVICES OTHER THAN PHYSICIANS’ SERVICES**

Section 602(k) of Pub. L. 98–21, as amended by Pub. L. 99–272, title IX, § 9112(a), Apr. 7, 1986, 100 Stat. 163, provided that:

"(1) The Secretary of Health and Human Services may, for any cost reporting period beginning prior to October 1, 1986, waive the requirements of sections 1862(a)(14) and 1866(a)(1)(H) of the Social Security Act [subsec. (a)(14) of this section and section 1395cc(a)(1)(H) of this title] in the case of a hospital which has followed a practice, since prior to October 1, 1982, of allowing direct billing under part B of title XVIII of the Social Security Act (other than physicians’ services) so extensively, that immediate compliance with those requirements would threaten the stability of patient care. Any such waiver shall provide that such billing may continue to be made under part B of such title but that the payments to such hospital under part A of such title (part A of this subchapter) shall be reduced by the amount of the billings for such services under part B of such title. If such a waiver is granted, at the end of the waiver period the Secretary may provide for such methods of determining payments under part A as is appropriate, given the organizational structure of the institution.

"(2) In the case of a hospital which is receiving payments pursuant to a waiver under paragraph (1), payment of the adjustment for indirect costs of approved educational activities shall be made as if the hospital were receiving under part A of title XVIII of the Social Security Act all the payments which are made under part B of such title solely by reason of such waiver.

"(3) Any waiver granted under paragraph (1) shall provide that, with respect to those items and services allied under part B of title XVIII of the Social Security Act solely by reason of such waiver—

"(A) payment under such part shall be equal to 100 percent of the reasonable charge or other applicable payment base for the items and services; and

"(B) the entity furnishing the items and services must agree to accept the amount paid pursuant to subparagraph (A) as the full charge for the items and services."

{Section 9112(b) of Pub. L. 99–272 provided that:}

"(11) Section 602(k)(2) of the Social Security Amendment of 1983 (as added by subsection (a) [set out above]) shall apply to cost reporting periods beginning on or after January 1, 1986.

"(12) Section 602(k)(3) of the Social Security Amendment of 1983 (as added by subsection (a) [set out above]) shall apply to items and services furnished after the end of the 10-day period beginning on the date of the enactment of this Act [Apr. 7, 1986]."

**PROHIBITION OF PAYMENT FOR INEFFECTIVE DRUGS**

Section 115(b) of Pub. L. 97–248 provided that: "No provision of law limiting the use of funds for purposes of enforcing or implementing section 1862(c) [subsec. (c) of this section] or section 1903(i)(5) [section 1396b(i)(5) of this title] of the Social Security Act, section 2103 of the Omnibus Budget Reconciliation Act of 1981 [section 2103 of Pub. L. 97–35, amending sections 1395y and 1396b of this title and enacting provisions set out as notes under sections 1395y and 1396b of this title], or any rule or regulation issued pursuant to any such section (including any provision contained in, or incorporated by reference into, any appropriation Act or resolution making continuing appropriations) shall apply to any period after September 30, 1982, unless such provision of law is enacted after the date of the enactment of such Act [Sept. 3, 1982] and specifically states that such provision is to supersede this section."

**ESTABLISHMENT AND IMPLEMENTATION OF GUIDELINES**

Section 2152(b) of Pub. L. 97–35 directed the Secretary of Health and Human Services to establish, and provide for the implementation of, the guidelines described in subsec. (f) of this section not later than Oct. 1, 1981.

**REPORT TO CONGRESSIONAL COMMITTEES ON IMPLEMENTATION OF CERTIFICATION REQUIREMENTS: RELATING TO MODIFICATION OF HEALTH BENEFITS PLAN OR PROGRAM; FAILURE TO SUBMIT REPORT**

Section 4(b) of Pub. L. 93–480 provided that the Civil Service Commission and the Secretary of Health, Education, and Welfare submit a report on or before Mar. 1, 1975, on the steps which have been taken, and the steps which are planned, to enable the Secretary to make the determination and certification referred to in former subsec. (c) of this section and that if such report is not submitted by Mar. 1, 1975, the date specified in former subsec. (c) shall be deemed to be July 1, 1975, rather than Jan. 1, 1976.
Consultation with State agencies and other organizations to develop conditions of participation for providers of services

In carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and (dd)(2), and (mm)(I) of section 1395x of this title, the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies. Such conditions prescribed under any of such subsections may be varied for different areas or different classes of institutions or agencies and may, at the request of a State, provide higher requirements for such State than for other States; except that, in the case of any State or political subdivision of a State which imposes higher requirements on institutions as a condition to the purchase of services (or of certain specified services) in such institutions under a State plan approved under subchapter I, XVI, or XIX of this chapter, the Secretary shall impose like requirements as a condition to the payment for services (or for the services specified by the State or subdivision) in such institutions in such State or subdivision.


REFERENCES IN TEXT


Amendments

1994—Pub. L. 103–432 struck out “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title,” before “the Secretary shall consult.”

1990—Pub. L. 101–508 inserted “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title,” after “subsection 1395x(a)(2)(F)(1) of this title,”.

1989—Pub. L. 101–239 substituted “(j)(3), and (mm)(I)” for “(j)(3)”.

1985—Pub. L. 100–234 repealed Pub. L. 100–360, §§ 203(c)(2), 204(c)(1), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted. In the case of the amendment by Pub. L. 100–360, § 203(c)(2), Pub. L. 101–234 was given effect by substituting “and

1 See References in Text note below.

2 So in original. The word “and” probably should not appear.
Effective Date of 1980 Amendment
Amendment by section 933(c) 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(b) of Pub. L. 96–499, set out as a note under section 1395k of this title.

Effective Date of 1972 Amendment
Amendment by Pub. L. 92–663 applicable with respect to providers of services for fiscal years beginning after the fifth month following October 1972, see section 234(i) of Pub. L. 92–663, set out as a note under section 1395x of this title.

Termination of Advisory Councils
Advisory councils in existence on Jan. 5, 1973, to terminate not later than the expiration of the 2-year period following Jan. 5, 1973, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, 778, set out in the Appendix to Title 5, Government Organization and Employees.

§ 1395aa. Agreements with States

(a) Use of State agencies to determine compliance by providers of services with conditions of participation

The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or whether an agency therein is a home health agency, or whether an agency is a hospice program or whether a facility therein is a rural health clinic as defined in section 1395x(aa)(2) of this title, a critical access hospital, as defined in section 1395x(mm)(1) of this title, or a comprehensive outpatient rehabilitation facility as defined in section 1395x(cc)(2) of this title, or whether a laboratory meets the requirements of paragraphs (16) and (17) of section 1395x(s) of this title, or whether a clinic, rehabilitation agency or public health agency meets the requirements of subparagraph (A) or (B), as the case may be, of section 1395p(p)(4) of this title, or whether an ambulatory surgical center meets the standards specified under section 1395k(a)(2)(P')(1) of this title. To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local agency) certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or home health agency, when that survey was completed, such health care facility, ambulatory surgical center, comprehensive outpatient rehabilitation facility, laboratory, clinical agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients’ representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinical agency, or organization with (1) the statutory conditions of participation imposed under this subchapter and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care by any such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinical agency, or organization. Any agreement under this subsection shall provide for the appropriate State or local agency to maintain a toll-free hotline (1) to collect, maintain, and continually update information on home health agencies located in the State or locality that are certified to participate in the program established under subchapter (which information shall include any significant deficiencies found with respect to patient care in the most recent certification survey conducted by a State agency or accreditation survey conducted by a private accreditation agency under section 1395bb of this title with respect to the home health agency, when that survey was completed, and (2) to receive complaints (and answer questions) with respect to home health agencies in the State or locality. Any such agreement shall provide for such State or local agency to maintain a unit for investigating such complaints that possesses enforcement authority and has access to survey and certification reports, information gathered by any private accreditation agency utilized by the Secretary under section 1395bb of this title, and consumer medical records (but only with the consent of the consumer or his or her legal representative).

(b) Payment in advance or by way of reimbursement to State for performance of functions of subsection (a)

The Secretary shall pay any such State, in advance or by way of reimbursement, as may be provided in the agreement with it (and may make adjustments in such payments on account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (a) of this section, and for the Federal Hospital Insurance Trust Fund’s fair share of the costs attributable

1395i–3(a) of this title. Any such services furnished by a State agency shall be deemed to have been furnished pursuant to such agreement. Within 90 days following the completion of each survey of any health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinical agency, or organization by the appropriate State or local agency described in the first sentence of this subsection, the Secretary shall make public in readily available form and place, and require (in the case of skilled nursing facilities) the posting in a place readily accessible to patients (and patients’ representatives), the pertinent findings of each such survey relating to the compliance of each such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinical agency, or organization with (1) the statutory conditions of participation imposed under this subchapter and (2) the major additional conditions which the Secretary finds necessary in the interest of health and safety of individuals who are furnished care by any such health care facility, ambulatory surgical center, rural health clinic, comprehensive outpatient rehabilitation facility, laboratory, clinical agency, or organization.
to the planning and other efforts directed toward coordination of activities in carrying out its agreement and other activities related to the provision of services similar to those for which payment may be made under part A of this subchapter, or related to the facilities and personnel required for the provision of such services, or related to improving the quality of such services.

(c) Use of State or local agencies to survey hospitals

The Secretary is authorized to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) of this section will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), provider entities that, pursuant to section 1395bb(a)(1) of this title, are treated as meeting the conditions or requirements of this subchapter. The Secretary shall pay for such services in the manner prescribed in subsection (b) of this section.

(d) Fulfillment of requirements by States

The Secretary may not enter an agreement under this section with a State with respect to determining whether an institution therein is a skilled nursing facility unless the State meets the requirements specified in section 1395i–3(e) of this title and section 1395i–3(g) of this title and the establishment of remedies under sections 1395i–3(b)(2)(B) and 1395i–3(b)(2)(C) of this title (relating to establishment and application of remedies).

(e) Prohibition of user fees for survey and certification

Notwithstanding any other provision of law, the Secretary may not impose, or require a State to impose, any fee on any facility or entity subject to a determination under subsection (a) of this section, or any renal dialysis facility subject to the requirements of section 1395rr(b)(1) of this title, for any such determination or any survey relating to determining the compliance of such facility or entity with any requirement of this subchapter (other than any fee relating to section 263a of this title).


REFERENCES IN TEXT

Part A of this subchapter, referred to in subsec. (b), is classified to section 1395c et seq. of this title.

AMENDMENTS

2008—Subsec. (c). Pub. L. 110–275 substituted “pursuant to section 1395bb(a)(1)’’ for “pursuant to subsection (a) or (b)(1) of section 1395bb’’.

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

Pub. L. 105–33, § 4106(c), substituted “paragraphs (16) and (17)” for “paragraphs (15) and (16)’’.

1996—Subsec. (c). Pub. L. 104–134, in first sentence, substituted at end “provider entities that, pursuant to subsection (a) or (b)(1) of section 1395bb of this title, are treated as meeting the conditions or requirements of this subchapter.” for “hospitals which have an agreement with the Secretary under section 1395cc of this title and which are accredited by the Joint Commission on Accreditation of Hospitals’’.

1994—Subsec. (a). Pub. L. 103–432, § 160(a)(1)(B), struck out “or (in the case of a laboratory that does not participate or seek to participate in the medicare program) the requirements of section 263a of this title’’ after “section 1395x(s) of this title’’.

Pub. L. 103–432, § 1160(a)(1)(B), struck out “section 1395x(s) of this title or (in the case of a laboratory that does not participate or seek to participate in the medicare program) the requirements of section 263a of this title’’ after “section 1395x(s) of this title’’.

1990—Subsec. (a). Pub. L. 101–508, § 4163(c)(2), inserted before period at end “other than any fee relating to section 263a of this title’’.

Subsec. (e). Pub. L. 101–508, § 4154(d)(1), substituted “section 1395x(s) of this title or (in the case of a laboratory that does not participate or seek to participate in the medicare program) the requirements of section 263a of this title’’ for “section 1395x(s) of this title’’.


1989—Subsec. (a). Pub. L. 101–239, § 6115(c), substituted “paragraphs (15) and (16)” for “paragraphs (14) and (15)’’.

Pub. L. 101–239, § 6003(g)(3)(C)(iii), inserted “a rural primary care hospital, as defined in section 1395x(mm)(1)(A) of this title’’ after “section 1395x(a)(11)’’ of this title’’.

Pub. L. 101–234 repealed Pub. L. 100–360, §§ 203(e)(3), 204(c)(2), (d)(3), and provided that the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted, see 1988 and 1989 Amendment notes.
1986—Subsec. (a). Pub. L. 99–369 substituted “paragraphs (12) and (13)” for “paragraphs (11) and (12)”.
1984—Subsec. (c). Pub. L. 98–569 struck out “the” after “Joint Commission on”.
1982—Subsec. (a). Pub. L. 97–248 inserted “whether an agency is a hospice program” and substituted “home health agency, or hospice program” for “home health agency”.
1980—Subsec. (a). Pub. L. 96–611 substituted “requirements of paragraphs (11) and (12) of section 1395x(s) of this title” for “requirements of paragraphs (10) and (11) of section 1395x(s) of this title”.
1979—Subsec. (a). Pub. L. 96–499, §934(c)(2), inserted “or a comprehensive outpatient rehabilitation facility as defined in section 1395x(c)(2) of this title” after “section 1395x(aa)(2) of this title” and “comprehensive outpatient rehabilitation facility,” after “rural health clinic,” in four places.
1977—Subsec. (a). Pub. L. 95–210 expanded enumeration of institutions and agencies included under coverage of this subsection by inserting references to rural health clinics in five places.
1972—Subsec. (a). Pub. L. 92–603, §§277, 278(a)(16), (b)(15), 290(a), provided for the furnishing of specialized consultative services to skilled nursing facilities, authorized the Secretary to make public the pertinent findings of each survey within 90 days following the completion of each survey of any health care facility, etc., and substituted “skilled nursing facility” for “extended care facility”.
Subsec. (c). Pub. L. 92–603, §244(a), added subsec. (c).
1969—Subsec. (a). Pub. L. 90–248, §138(f), inserted clause at end of first sentence for determining whether a clinic, rehabilitation agency, or public health agency meets the requirements of section 1395x(p)(4)(A) or (B) of this title.
1968—Subsec. (a). Pub. L. 90–248, §226(b), struck out last sentence providing for utilization of State facilities to provide consultative services to institutions furnishing medical care, covered in section 1396(a)(24) of this title.

**Effective Date of 2008 Amendment; Transition Rule**

Amendment by Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(c) of Pub. L. 110–275, set out as a note under section 1395bb of this title.

**Effective Date of 1997 Amendment**

Amendment by section 4106(c) of Pub. L. 105–33 applicable to bone mass measurements performed on or after July 1, 1998, see section 4106(d) of Pub. L. 105–33, set out as a note under section 1396x of this title.

**Effective Date of 1994 Amendment**

Amendment by section 145(c)(3) of Pub. L. 103–432 applicable to mammography furnished by a facility on and after the first date that the certificate requirements of section 263(b)(1) 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.

**Effective Date of 1990 Amendment**

Section 415(d)(2) of Pub. L. 101–508 provided that: “The amendment made by paragraph (1) [amending this
section] shall take effect as if included in the enactment of the Clinical Laboratory Improvement Amendments of 1988 [Pub. L. 100–578].

Amendment by section 4163(c)(2) of Pub. L. 101–508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4163(e)(c) of Pub. L. 101–508, set out as a note under section 1395l of this title.

**Effective Date of 1989 Amendments**

Amendment by section 6115(c) of Pub. L. 101–238 applicable to screening pap smears performed on or after July 1, 1990, see section 6115(d) of Pub. L. 101–239, set out as a note under section 1395x of this title.

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a–7a of this title.

**Effective Date of 1988 Amendments**

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Health Insurance Act of 1988, Pub. L. 100–360, see section 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 228(b) of Pub. L. 90–248 applicable to items and services furnished on or after Jan. 1, 1990, see section 228(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Amendment by section 228(b) of Pub. L. 100–360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 228(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.


For effective date of amendment by section 4972(d) of Pub. L. 100–203, see section 4972(e) of Pub. L. 100–203, set out as a note under section 1395x of this title.

Amendments by sections 4201(a)(2), (d)(4) and 4202(a)(1), (c) of Pub. L. 100–203 applicable to services furnished on or after Oct. 1, 1990, without regard to whether regulations to implement such amendments are promulgated by such date, except as otherwise specifically provided in section 1395j–3 of this title, see section 4204(a) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1395j–3 of this title.

Amendment by section 4203(a)(1) of Pub. L. 100–203 applicable Jan. 1, 1988, except as otherwise specifically provided in section 1395j–3 of this title, without regard to whether regulations to implement such amendment are promulgated by such date, and in applying amendment by section 4203(a)(1) of Pub. L. 100–203 for services furnished by a skilled nursing facility before Oct. 1, 1990, any reference to a requirement of section 1395j–3(b), (c), or (d) of this title is deemed a reference to section 1395j of this title, see section 4204(b) of Pub. L. 100–203, as added by Pub. L. 100–485, set out as an Effective Date note under section 1395j–3 of this title.

**Effective Date of 1986 Amendment**

Amendment by 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 19320(d)(4) of Pub. L. 99–509, as amended, set out as notes under section 1395k of this title.

**Effective Date of 1984 Amendment**

Amendment by 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(c)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1982 Amendment**

Amendment by Pub. L. 97–248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97–248, as amended, set out as a note under section 1395c of this title.

**Effective Date of 1980 Amendments**

Amendment by Pub. L. 96–613 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96–611, set out as a note under section 1395k of this title.

Amendment by section 203(e)(3) of Pub. L. 100–360 applicable to services furnished on or after Jan. 1, 1990, see section 204(e)(1) of Pub. L. 96–611, set out as a note under section 1395k of this title.

Amendment by Pub. L. 95–210 applicable to services rendered on or after first day of third calendar month which begins after Dec. 31, 1977, see section 1(l) of Pub. L. 95–210, set out as a note under section 1395k of this title.

**Effective Date of 1972 Amendment**

Amendment by Pub. L. 96–613 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96–611, set out as a note under section 1395k of this title.

**Effective Date of 1968 Amendment**

Amendment by section 133(f) of Pub. L. 90–248 applicable with respect to services furnished after June 30, 1968, see section 133(g) of Pub. L. 90–248, set out as a note under section 1395k of this title.

Section 228(b) of Pub. L. 90–248 provided that the amendment made by such section 228(b) is effective July 1, 1969.

**Use of State or Local Agencies in Evaluating Laboratories**

Section 160(a)(2) of Pub. L. 103–432 provided that: "An agreement made by the Secretary of Health and Human Services with a State under section 1864(a) of the Social Security Act [subsec. (a) of this section] may include an agreement that the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by the Secretary for the purpose of determining whether a laboratory meets the requirements of section 353 of the Public Health Service Act [section 263a of this title]."

**Nurse Aid Training and Competency Evaluation, Failure by State To Meet Guidelines**

Section 4008(h)(1)(A) of Pub. L. 101–508 provided that: "The Secretary of Health and Human Services may not refuse to enter into an agreement or cancel an existing agreement with a State under section 1864 of the Social Security Act [this section] on the basis that the State failed to meet the requirement of section 1819(e)(1)(A) of such Act [section 1819(e)(1)(A) of this title] before the effective date of guidelines, issued by the Secretary, establishing requirements under section 1819(e)(2)(A) of such Act, if the State demonstrates to the satisfaction of the Secretary that it has made a good faith effort to meet such requirement before such effective date."
§ 1395bb. Effect of accreditation

(a) Accreditation by American Osteopathic Association or other national accreditation body

(1) If the Secretary finds that accreditation of a provider entity (as defined in paragraph (d)) by the American Osteopathic Association or any other national accreditation body demonstrates that all of the applicable conditions or requirements of section 1395m(j) of this title (or the conditions and requirements under section 1395rr(b) of this title) are met or exceeded—

(A) in the case of a provider entity not described in paragraph (3)(B), the Secretary shall treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding; or

(B) in the case of a provider entity described in paragraph (3)(B), the Secretary may treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding.

(2) In making such a finding, the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

(3)(A) Except as provided in subparagraph (B), not later than 60 days after the date of receipt of a written request for a finding under paragraph (1) (with any documentation necessary to make a determination on the request), the Secretary shall publish a notice identifying the national accreditation body making the request, describing the nature of the request, and providing a period of at least 30 days for the public to comment on the request. The Secretary shall accept or deny a request for such a finding, and shall publish notice of such approval or denial, not later than 210 days after the date of receipt of the request (with such documentation). Such an approval shall be effective with respect to the request (with such documentation). Such approval shall be effective with respect to the request (with such documentation).

(B) The 210-day and 60-day deadlines specified in subparagraph (A) shall not apply in the case of any request for a finding with respect to accreditation of a provider entity to which the conditions and requirements of sections 1395i-3 and 1395x(j) of this title apply.

(4) For purposes of this section, the term “provider entity” means a provider of services, supplier, facility, clinic, agency, or laboratory.

(b) Disclosure of accreditation survey

The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopathic Association or any other national accreditation body of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary.

(c) Deficiencies

Notwithstanding any other provision of this subchapter, if the Secretary finds that a provider entity has significant deficiencies (as defined in regulations pertaining to health and safety), the entity shall, after the date of notice of such finding to the entity and for such period as may be prescribed in regulations, be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to subsection (a)(1).

(d) State or local accreditation

For provisions relating to validation surveys of entities that are treated as meeting applicable conditions or requirements of this subchapter pursuant to subsection (a)(1), see section 1385aa(c) of this title.


AMENDMENTS

2008—Subsec. (a). Pub. L. 110–275, §125(a), redesignated subsec. (b) as (a) and struck out former subsec. (a) which provided criteria necessary for an institution to meet certain requirements enumerated in section 1395x(e) of this title.

Subsec. (a)(1). Pub. L. 110–275, §125(b)(1)(A), substituted “II” for “In addition, II”.

Subsec. (b). Pub. L. 110–275, §125(a), (b)(1)(B), redesignated subsec. (c) as (b), substituted “released to the Secretary by” for “released to him by the Joint Commission on Accreditation of Hospitals,”, and struck out the comma after “Osteopathic Association”. Former subsec. (b) redesignated (a).

Subsecs. (c), (d). Pub. L. 110–275, §125(a), (b)(1)(C), (D), redesignated subsecs. (d) and (e) as (c) and (d), respectively, and substituted “pursuant to subsection (a)(1)” for “pursuant to subsection (a) or (b)(1)”. Former subsec. (c) redesignated (b).

Subsec. (e). Pub. L. 110–275, §125(a), redesignated subsec. (e) as (d).


1996—Subsec. (a)(9). Pub. L. 104–140, §8(b), substituted “as determined in paragraphs (1) through (6)” for “as determined by paragraphs (1) through (6)”. Former subsec. (a)(9), redesignated (a)(10).
1996—Subsec. (a). Pub. L. 104–134, §101(d) [title V, §516(b)(2), (3)], struck out after second sentence: “In addition, if the Secretary finds that accreditation of an entity by the American Osteopathic Association or any other national accreditation body provides reasonable assurance that any or all of the conditions of sections 1395x(a)(2)(F)(1), 1395x(e), 1395x(f), 1395x(j), 1395x(o), 1395x(p)(4)(A) or (B), paragraphs (15) and (16) of section 1395x(s), section 1395aa(a)(2), 1395cc(c)(2), 1395dd(d)(2), or 1395mm(1) of this title, as the case may be, are met, he may, to the extent he deems it appropriate, treat such entity as meeting the condition or conditions with respect to which he made such finding,” and redesignated fourth sentence as subsection (c).

Subsec. (b). Pub. L. 104–134, §101(d) [title V, §516(b)(2)], added subsection (b). Former subsection (d) redesignated (d).

Subsec. (c). Pub. L. 104–134, §101(d) [title V, §516(c)(2)], redesignated fourth sentence of subsection (a) as subsection (c).

Subsec. (d). Pub. L. 104–134, §101(d) [title V, §516(b)(1), (c)(2)(A)], redesignated subsection (b) as (d) and subsection (d) as (c). Pub. L. 104–132 struck out “‘hospital’” for “‘the hospital’” in two places, and “‘the requirements or conditions the entity has been treated as meeting pursuant to subsection (a) or (b)(1) of this section’” for “‘the requirements of the numbered paragraphs of section 1395x(e) of this title’”.

Subsec. (e). Pub. L. 104–134, §101(d) [title V, §516(c)(2)(B)], added subsection (e).


1989—Subsec. (a). Pub. L. 101–239, §6115(c), substituted ‘‘paragraphs (15) and (16)’’ for ‘‘paragraphs (14) and (15)’’.

Pub. L. 101–239, §6019(b), inserted before period at end ‘‘, except that the Secretary may disclose such a survey and information related to such a survey to the extent such survey and information relate to an enforcement action taken by the Secretary’’.

1988—Subsec. (a). Pub. L. 100–360, §411(d)(4)(B)(ii), substituted ‘‘1395x(dd)(2), or 1395mm(1) of this title’’ for ‘‘1395x(dd)(2) of this title’’ in third sentence.

Pub. L. 101–234 repealed Pub. L. 100–360, §204(d)(3), substituted ‘‘paragraphs (14) and (15)’’ for ‘‘paragraphs (14) and (15)’’.

1985—Subsec. (a). Pub. L. 99–509, §1229(g)(4), substituted ‘‘(a)’’ for ‘‘(o)’’.

Subsec. (b). Pub. L. 97–248, §128(b)(3), substituted ‘‘a hospital for an institution and the hospital’’ for ‘‘such institution’’.

1982—Subsec. (a). Pub. L. 97–248, §1229(g)(4), substituted ‘‘(o), (dd)’’ for ‘‘(or (o))’’.

Subsec. (b). Pub. L. 97–248, §128(b)(3), substituted ‘‘a hospital for an institution and the hospital’’ for ‘‘such institution’’.

1981—Subsec. (a). Pub. L. 92–603 designated existing provisions as subsections, added reference to subsection (b) of this section in opening provisions, redesignated existing provisions as paragraphs (1) and (3) and added paragraphs (2) and (4) and in provisions following paragraph 4, inserted provisions for the imposition of a standard which the Secretary determines is at least equivalent to the standard promulgated by the Secretary as described in paragraph (4), and added subsection (b).

**Effective Date of 2008 Amendment; Transition Rule**

Pub. L. 110–275, title I, §125(d), July 15, 2008, 122 Stat. 2520, provided that:

‘‘(1) Subject to paragraph (2), the amendments made by this section [amending this section and sections 1395m, 1395w–22, 1395x, 1395aa, and 1395l of this title] shall apply with respect to accreditations of hospitals granted on or after the date that is 24 months after the date of the enactment of this Act [July 15, 2008].’’

‘‘(2) For purposes of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), the amendments made by this section shall not affect [sic] the accreditation of a hospital by the Joint Commission, or under accreditation or comparable approval standards found to be essentially equivalent to accreditation or approval standards of the Joint Commission, for the period of time applicable under such accreditation.’’

**Effective Date of 1994 Amendment**

Amendment by Pub. L. 103–432 applicable to mammography furnished by a facility on and after the first date that the certificate requirements of section 2630(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.

**Effective Date of 1990 Amendment**

Amendment by 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 1395bb of this title.

**Effective Date of 1989 Amendments**

Section 6019(d) of Pub. L. 101–239 provided that:

‘‘(1) Except as provided in paragraph (2), the amendments made by this section [amending this section] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].’’

‘‘(2) The amendments made by subsection (a) [amending this section] shall take effect 6 months after the date of the enactment of this Act.’’
Amendment by section 6115(c) of Pub. L. 101–239 applicable to screening mammograms performed on or after July 1, 1990, see section 6115(d) of Pub. L. 101–239, set out as a note under section 1395x of this title.

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a–7a of this title.

**Effective Date of 1988 Amendments**

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 6088(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 204(c)(3), (d)(3) of Pub. L. 100–360 applicable to screening mammography performed on or after Jan. 1, 1990, see section 204(e) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(d)(4)(B)(ii) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a reference to OBRA; Effective Date note under section 106 of Title I, General Provisions.

**Effective Date of 1987 Amendment**

Amendment by section 4025(b) of Pub. L. 100–203 applicable with respect to agreements entered into or renewed on or after Dec. 22, 1987, see section 4025(c) of Pub. L. 100–203, as amended, set out as a note under section 1395aa of this title.

For effective date of amendment by section 4972(d) of Pub. L. 100–203, see section 4972(e) of Pub. L. 100–203, set out as a note under section 1395x of this title.

**Effective Date of 1986 Amendment**

Amendment by section 9305(c)(3) of Pub. L. 99–509 applicable to hospitals as of one year after Oct. 21, 1986, see section 9305(c)(4) of Pub. L. 99–509, set out as a note under section 1395x of this title.

Amendment by section 9320(h)(3) 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(h)(1), (k) of Pub. L. 99–509, as amended, set out as notes under section 1395x of this title.

**Effective Date of 1984 Amendment**

Section 2345(b) of Pub. L. 98–369 provided that: “The amendments made by this section [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984], and shall apply with respect to surveys released to the Secretary on, before, or after such date.”

Section 2346(b) of Pub. L. 98–369 provided that: “The amendments made by this section [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984].”

**Effective Date of 1982 Amendment**

Amendment by section 122(g)(4) of Pub. L. 97–248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(3) of Pub. L. 97–248, as amended, set out as a note under section 1395c of this title.


**Effective Date of 1972 Amendment**

Amendment by section 234(b) of Pub. L. 92–603 applicable with respect to providers of services for fiscal years beginning after the fifth month following October 1972, see section 234(a) of Pub. L. 92–603, set out as a note under section 1395x of this title.

**Authority To Recognize the Joint Commission as a National Accreditation Body**

Pub. L. 110–275, title I, § 125(c), July 15, 2008, 122 Stat. 2519, provided that: “The Secretary of Health and Human Services may recognize the Joint Commission as a national accreditation body under section 1865 of the Social Security Act (42 U.S.C. 1395bb), as amended by this section, upon such terms and conditions, and upon submission of such information, as the Secretary may require.”

**§ 1395cc. Agreements with providers of services; enrollment processes**

(a) Filing of agreements; eligibility for payment; charges with respect to items and services

(1) Any provider of services (except a fund designated for purposes of section 1395g and section 1395m(e) of this title) shall be qualified to participate under this subchapter and shall be eligible for payments under this subchapter if it files with the Secretary an agreement—

(A)(i) not to charge, except as provided in paragraph (2), any individual or any other person for items or services for which such individual is entitled to have payment made under this subchapter (or for which he would be so entitled if such provider of services had complied with the procedural and other requirements under or pursuant to this subchapter or for which such provider is paid pursuant to the provisions of section 1395(e) of this title), and (ii) to make adequate provision for return of such items or services under this subchapter because payment for expenses incurred for such items or services may not be made by reason of the provisions of paragraph (1) or (9) of section 1395(y)(a) of this title, but only if (i) such individual was without fault in incurring such expenses and (ii) the Secretary’s determination that such payment may not be made for such items and services was made after the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter,

(C) to make adequate provision for return (or other disposition, in accordance with regulations) of any moneys incorrectly collected from such individual or other person,

(D) to promptly notify the Secretary of its employment of an individual who, at any time during the year preceding such employment, was employed in a managerial, accounting, auditing, or similar capacity (as determined by the Secretary by regulation) by an agency or organization which serves as a fiscal intermediary or carrier (for purposes of part A or part B, or both, of this subchapter) with respect to the provider,

(E) to release data with respect to patients of such provider upon request to an organization having a contract with the Secretary under part B of subchapter XI of this chapter as may be necessary (i) to allow such organization to carry out its functions under such con-
tract, or (ii) to allow such organization to carry out similar review functions under any contract the organization may have with a private or public agency paying for health care in the same area with respect to patients which authorize release of such data for such purposes,

(F)(i) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b), (c), or (d) of section 1395ww of this title, to maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a utilization and quality control peer review organization which has a contract with the Secretary under part B of subchapter XI of this chapter for the area in which the hospital is located, under which the organization will perform functions under that part with respect to the review of the appropriateness of care provided for which payment may be made under part A of this subchapter (and for purposes of payment under this subchapter, the cost of such agreement to the hospital shall be considered a cost incurred by such hospital in providing inpatient services under part A of this subchapter, and (I) shall be paid directly by the Secretary to such organization on behalf of such hospital in accordance with a rate per review established by the Secretary. (II) shall be transferred from the Federal Hospital Insurance Trust Fund, without regard to amounts appropriated in advance in appropriation Acts, in the same manner as transfers are made for payment for services provided directly to beneficiaries, and (III) shall not be less in the aggregate for a fiscal year than the aggregate amount expended in fiscal year 1988 for direct and administrative costs (adjusted for inflation and for any direct or administrative costs incurred as a result of review functions added with respect to a subsequent fiscal year) of such reviews),

(ii) in the case of hospitals, critical access hospitals, skilled nursing facilities, and home health agencies, to maintain an agreement with a utilization and quality control peer review organization (which has a contract with the Secretary under part B of subchapter XI of this chapter for the area in which the hospital, facility, or agency is located) to perform the functions described in paragraph (3)(A).

(G) in the case of hospitals which provide inpatient hospital services for which payment may be made under subsection (b) or (d) of section 1395ww of this title, not to charge any individual or any other person for inpatient hospital services for which such individual would be entitled to have payment made under part A of this subchapter but for a denial or reduction of payments under section 1395ww(f)(2) of this title,

(H)(i) in the case of hospitals which provide services for which payment may be made under this subchapter and in the case of critical access hospitals which provide critical access hospital services, to have all items and services (other than physicians’ services as defined in regulations for purposes of section 1395x(s)(2)(D) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist) that are furnished to an individual who is a patient of the hospital, and (II) for which the individual is entitled to have payment made under this subchapter, furnished by the hospital or otherwise under arrangements (as defined in section 1395x(w)(1)(I) of this title) made by the hospital,

(i) that are furnished to an individual who is a resident of the skilled nursing facility during a period in which the resident is provided covered post-hospital extended care services (or, for services described in section 1395x(s)(2)(D) of this title, that are furnished to such an individual without regard to such period), and

(ii) for which the individual is entitled to have payment made under this subchapter, to have items and services (other than services described in section 1395x(e)(2)(A)(ii) of this title) furnished by the skilled nursing facility or otherwise under arrangements (as defined in section 1395x(w)(1)(I) of this title) made by the skilled nursing facility,

(i) in the case of a hospital or critical access hospital—

(1) to adopt and enforce a policy to ensure compliance with the requirements of section 1395dd of this title and to meet the requirements of such section,

(ii) to maintain medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer, and

(iii) to maintain a list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition.

(J) in the case of hospitals which provide inpatient hospital services for which payment may be made under this subchapter, to be a participating provider of medical care under any health plan contracted for under section 1079 or 1086 of title 10, or under section 1713 of title 38, in accordance with admission practices, payment methodology, and amounts as prescribed under joint regulations issued by the Secretary and by the Secretaries of Defense and Transportation, in implementation of sections 1079 and 1086 of title 10,

(K) not to charge any individual or any other person for items or services for which payment under this subchapter is denied under section 1320c–3(a)(2) of this title by reason of a determination under section 1320c–3(a)(1)(B) of this title,

1 See References in Text note below.
(L) In the case of hospitals which provide inpatient hospital services for which payment may be made under this subchapter, to be a participating provider of medical care under section 1703 of title 38, in accordance with such admission practices, and such payment methodology and amounts, as are prescribed under joint regulations issued by the Secretary and by the Secretary of Veterans Affairs in implementation of such section.

(M) In the case of hospitals, to provide to each individual who is entitled to benefits under part A of this subchapter (or to a person acting on the individual's behalf), at or about the time of the individual's admission as an inpatient to the hospital, a written statement (containing such language as the Secretary prescribes consistent with this paragraph) which explains—

1. The individual's rights to benefits for inpatient hospital services and for post-hospital services under this subchapter,
2. The circumstances under which such an individual will and will not be liable for charges for continued stay in the hospital,
3. The individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and
4. The individual's liability for payment for services if such a denial of benefits is upheld on appeal,

and which provides such additional information as the Secretary may specify.

(N) In the case of hospitals and critical access hospitals—

1. To make available to its patients the directory or directories of participating physicians (published under section 1395u(h)(4) of this title) for the area served by the hospital or critical access hospital,
2. If hospital personnel (including staff of any emergency or outpatient department) refer a patient to a nonparticipating physician for further medical care on an outpatient basis, the personnel must inform the patient that the physician is a nonparticipating physician and, whenever practicable, must identify at least one qualified participating physician who is listed in such a directory and from whom the patient may receive the necessary services,
3. To post conspicuously in any emergency department a sign (in a form specified by the Secretary) specifying rights of individuals under section 1395dd of this title with respect to examination and treatment for emergency medical conditions and women in labor, and
4. To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the Medicaid program under a State plan approved under subchapter XIX of this chapter.

(O) To accept as payment in full for services that are covered under this subchapter and are furnished to any individual enrolled with a Medicare+Choice organization under part C of this subchapter, with a PACE provider under section 1395eee or 1396u-4 of this title, or with an eligible organization with a risk-sharing contract under section 1395mm of this title, under section 1395mm(i)(2)(A) of this title (as in effect before February 1, 1985), under section 1395h-1(a) of this title, or under section 222(a) of the Social Security Amendments of 1972, which does not have a contract (or, in the case of a PACE provider, contract or other agreement) establishing payment amounts for services furnished to members of the organization or PACE program eligible individuals enrolled with the PACE provider, the amounts that would be made as a payment in full under this subchapter (less any payments under sections 1395ww(d)(11) and 1395ww(h)(3)(D) of this title) if the individuals were not so enrolled,

(P) In the case of home health agencies which provide home health services to individuals entitled to benefits under this subchapter who require catheters, catheter supplies, ostomy bags, and supplies related to ostomy care (described in section 1395x(m)(5) of this title), to offer to furnish such supplies to such an individual as part of their furnishing of home health services,

(Q) In the case of hospitals, skilled nursing facilities, home health agencies, and hospice programs, to comply with the requirement of subsection (f) of this section (relating to maintaining written policies and procedures respecting advance directives),

(R) To contract only with a health care clearinghouse (as defined in section 1320d of this title) that meets each standard and implementation specification adopted or established under part C of subchapter XI of this chapter on or after the date on which the health care clearinghouse is required to comply with the standard or specification,

(S) In the case of a hospital that has a financial interest (as specified by the Secretary in regulations) in an entity to which individuals are referred as described in section 1395x(ee)(2)(H)(ii) of this title, or in which such an entity has such a financial interest, or in which another entity has such a financial interest (directly or indirectly) with such hospital and such an entity, to maintain and disclose to the Secretary (in a form and manner specified by the Secretary) information on—

1. The nature of such financial interest,
2. The number of individuals who were discharged from the hospital and who were identified as requiring home health services, and
3. The percentage of such individuals who received such services from such provider (or another such provider),

(T) In the case of hospitals and critical access hospitals, to furnish to the Secretary such data as the Secretary determines appropriate pursuant to subparagraph (E) of section 1395ww(d)(12) of this title to carry out such section,

(U) In the case of hospitals which furnish inpatient hospital services for which payment may be made under this subchapter, to be a participating provider of medical care both—

1. Under the contract health services program funded by the Indian Health Service.
and operated by the Indian Health Service, an Indian tribe, or tribal organization (as those terms are defined in section 1603 of title 25), with respect to items and services that are covered under such program and furnished to an individual eligible for such items and services under such program; and

(ii) under any program funded by the Indian Health Service and operated by an urban Indian organization with respect to the purchase of items and services for an eligible urban Indian (as those terms are defined in such section 1603),

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services.2

(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.] (or a State occupational safety and health plan that is approved under 18(b)3 of such Act [29 U.S.C. 667(b)]), to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated), and

(W)4 in the case of a hospital described in section 1395ww(d)(1)(B)(v) of this title, to report quality data to the Secretary in accordance with subsection (k).

(W)4 maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this subchapter, as specified by the Secretary.

In the case of a hospital which has an agreement in effect with an organization described in subparagraph (P) which organization’s contract with the Secretary under part B of subchapter XI of this chapter is terminated on or after October 1, 1984, the hospital shall not be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1395e(a)(1), (a)(3), or (a)(4), section 1395(b), or section 1395w(y)(3) of this title with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B of this subchapter or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1395(c) of this title, clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section. A provider of services may not impose a charge under clause (i) of the first sentence of this subparagraph with respect to items and services described in section 1395x(s)(10)(A) of this title and with respect to clinical diagnostic laboratory tests for which payment is made under part B of this subchapter. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items subject to payment under section 1395m(a) of this title, the amount of any deduction imposed under section 1395(b) of this title and 20 percent of the payment basis described in section 1395m(a)(1)(B) of this title in the case of items and services for which payment is made under part B of this subchapter under the prospective payment system established under section 1395l(t) of this title, clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1395l(t)(5)1 of this title. In the case of items described in section 1395l(a)(8) of this title or section 1395l(a)(9) of this title for which payment is made under part B of this subchapter under section 1395m(k) of this title, clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or the applicable fee schedule amount (as defined in such section) for such services.

(B) Where a provider of services has furnished, at the request of such 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 this subchapter, such provider of services may charge such individual or other person for such more expensive items or services to the extent that the amount customarily charged by it for the items or services furnished at such request exceeds the amount customarily charged by it for the items or services with respect to which payment may be made under this subchapter.

(C) A provider of services may in accordance with its customary practice also appropriately charge any such individual for any whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished him with respect to which a deductible is imposed under section 1395e(a)(2) of this title except that (i) any excess of such charge over the cost to such provider for the blood (or equivalent quantities of packed red blood cells, as so defined) shall be deducted from any payment to such provider under this subchapter, (ii) no such charge may be imposed for the cost of administration of such blood (or equivalent quantities of packed red blood cells, as so defined), and (iii) such charge may not be made to the extent such

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2So in original. The comma probably should be preceded by a closing parenthesis.
3So in original. Probably should be preceded by “section”.
4So in original. Two subpars. (W) have been enacted.
blood (or equivalent quantities of packed red blood cells, as so defined) has been replaced on behalf of such individual or arrangements have been made for its replacement on his behalf. For purposes of this subparagraph, whole blood (or equivalent quantities of packed red blood cells, as so defined) furnished such an individual shall be deemed replaced when the provider of services is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is imposed under section 1395x(a)(2) of this title.

(D) Where a provider of services customarily furnishes 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 this subchapter, such provider, notwithstanding the preceding provisions of this paragraph, may not, under the authority of subparagraph (B)(ii) of this paragraph, charge any individual or other person any amount for such items or services in excess of the amount of the payment which may otherwise be made for such items or services under this subchapter if the admitting physician has a direct or indirect financial interest in such provider.

(3)(A) Under the agreement required under paragraph (1)(F)(i), the peer review organization must perform functions (other than those covered under an agreement under paragraph (1)(F)(i)) under the third sentence of section 1395cc(a)(4)(A) of this title and under section 1320c–3(a)(14) of this title with respect to services, furnished by the hospital, critical access hospital, facility, or agency involved, for which payment may be made under this subchapter.

(B) For purposes of payment under this subchapter, the cost of such an agreement to the hospital, critical access hospital, facility, or agency involved, for which payment may otherwise be made under this subchapter if the admitting physician has a direct or indirect financial interest in such provider.

(c) Refiling after termination or nonrenewal; agreements with skilled nursing facilities

(b) Termination or nonrenewal of agreements

(1) A provider of services may terminate an agreement with the Secretary under this section at such time and upon such notice to the Secretary and the public as may be provided in regulations, except that notice of more than six months shall not be required.

(2) The Secretary may refuse to enter into an agreement under this section or, upon such reasonable notice to the provider and the public as may be specified in regulations, may refuse to renew or may terminate such an agreement after the Secretary has determined that the provider fails to comply substantially with the provisions of the agreement, with the provisions of this subchapter and regulations thereunder, or with a corrective action required under section 1395ww(f)(2)(B) of this title.

(C) has excluded the provider from participation in a program under this subchapter pursuant to section 1320a–7 of this title or section 1320a–7a of this title, or

(D) has ascertained that the provider has been convicted of a felony under Federal or State law for an offense which the Secretary determines is detrimental to the best interests of the program or program beneficiaries.

(3) A termination of an agreement or a refusal to renew an agreement under this subsection shall become effective on the same date and in the same manner as an exclusion from participation under the programs under this subchapter becomes effective under section 1320a–7(c) of this title.

(4)(A) A hospital that fails to comply with the requirement of subparagraph (a)(1)(V) of this section (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 [29 U.S.C. 666] for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U) of this section by a hospital that is subject to the provisions of such Act [29 U.S.C. 651 et seq.].

(C) A civil money penalty under this paragraph shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected under that section.

Refiling after termination or nonrenewal; agreements with skilled nursing facilities

(1) Where the Secretary has terminated or has refused to renew an agreement under this subchapter with a provider of services, such provider may not file another agreement under this subchapter unless the Secretary finds that the reason for the termination or nonrenewal has been corrected and the provider substantially meets the applicable provisions of this subchapter.

So in original. Probably should be subsection "(a)(1)(V)".
been removed and that there is reasonable assurance that it will not recur.

(2) Where the Secretary has terminated or has refused to renew an agreement under this subchapter with a provider of services, the Secretary shall promptly notify each State agency which administers or supervises the administration of a State plan approved under subchapter XIX of this chapter of such termination or non-renewal.

(d) Decision to withhold payment for failure to review long-stay cases

If the Secretary finds that there is a substantial failure to make timely review in accordance with section 1395x(k) of this title of long-stay cases in a hospital, he may, in lieu of terminating his agreement with such hospital, decide that, with respect to any individual admitted to such hospital after a subsequent date specified by him, no payment shall be made under this subchapter for inpatient hospital services (including inpatient psychiatric hospital services) after the 20th day of a continuous period of such services. Such decision may be made effective only after such notice to the hospital and to the public, as may be prescribed by regulations, and its effectiveness shall terminate when the Secretary finds that the reasons therefor have been removed and that there is reasonable assurance that it will not recur. The Secretary shall not make any such decision except after reasonable notice and opportunity for hearing to the institution or agency affected thereby.

(e) "Provider of services" defined

For purposes of this section, the term "provider of services" shall include—

(1) a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1395x(p)(4)(A) of this title (or meets the requirements of such section through the operation of subsection (g) or (l)(2) of section 1395x of this title), or if, in the case of a public health agency, such agency meets the requirements of section 1395x(p)(4)(B) of this title (or meets the requirements of such section through the operation of subsection (g) or (l)(2) of section 1395x of this title), or if

(b)(2) the written policies of the provider or organization respecting the implementation of advance directives;

(2) the written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient;

(B) in the case of a skilled nursing facility, at the time of the individual's admission as a resident;

(C) in the case of a home health agency, in advance of the individual's admission;

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of an eligible organization (as defined in section 1395mm(b) of this title) or an organization provided payments under section 1395(a)(1)(A) of this title or a Medicare+Choice organization, at the time of enrollment of the individual with the organization.

(3) In this subsection, the term "advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State) respecting the implementation of advance directives at facilities of the provider or organization; and

(f) Maintenance of written policies and procedures

(1) For purposes of subsection (a)(1)(Q) of this section and sections 1395i–3(c)(2)(E), 1395i(s), 1395w–25(f), and 1395bb(a)(6) of this title, the requirement of this subsection is that a provider of services, Medicare+Choice organization, or prepaid or eligible organization (as the case may be) maintain written policies and procedures with respect to all adult individuals receiving medical care by or through the provider or organization (A) to provide written information to such individual concerning—

(i) an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives (as defined in paragraph (3)), and

(ii) the written policies of the provider or organization respecting the implementation of such rights;

(B) to document in a prominent part of the individual's current medical record whether or not the individual has executed an advance directive;

(c) Subparagraph (C) shall not be construed as requiring the provision of care which conflicts with an advance directive.

(2) The written information described in paragraph (1)(A) shall be provided to an adult individual—

(A) in the case of a hospital, at the time of the individual's admission as an inpatient;

(B) in the case of a skilled nursing facility, at the time of the individual's admission as a resident;

(C) in the case of a home health agency, in advance of the individual's admission;

(D) in the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program, and

(E) in the case of an eligible organization (as defined in section 1395mm(b) of this title) or an organization provided payments under section 1395(a)(1)(A) of this title or a Medicare+Choice organization, at the time of enrollment of the individual with the organization.

(g) Penalties for improper billing

Except as permitted under subsection (a)(2) of this section, any person who knowingly and
willfully presents, or causes to be presented, a bill or request for payment inconsistent with an arrangement under subsection (a)(1)(H) of this section or in violation of the requirement for such an arrangement, is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a of this title.

(h) Dissatisfaction with determination of Secretary; appeal by institutions or agencies; single notice and hearing

(1)(A) Except as provided in paragraph (2), an institution or agency dissatisfied with a determination by the Secretary that it is not a provider of services or with a determination described in subsection (b)(2) of this section shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary’s final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(f) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, may obtain expedited access to judicial review under the process established under section 1395ff(b)(2) of this title. Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1395i-3 of this title during the pendency of an appeal under this subparagraph.

(C)(i) The Secretary shall develop and implement a process for expedite proceedings under this subsection in which—

(I) the remedy of termination of participation has been imposed;

(II) a remedy described in clause (i) or (ii) of section 1395i-3(h)(2)(B) of this title has been imposed, but only if such remedy has been imposed on an immediate basis; or

(III) a determination has been made as to a finding of substandard quality of care that results in the loss of approval of a skilled nursing facility’s nurse aide training program.

(ii) Under such process under clause (i), priority shall be provided in cases of termination described in clause (i)(I).

(iii) Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1395i-3 of this title during the pendency of an appeal under this subparagraph.

(2) An institution or agency is not entitled to separate notice and opportunity for a hearing under both section 1320a-7 of this title and this section with respect to a determination or determinations based on the same underlying facts and issues.

(i) Intermediate sanctions for psychiatric hospitals

(1) If the Secretary determines that a psychiatric hospital which has an agreement in effect under this section no longer meets the requirements for a psychiatric hospital under this subchapter and further finds that the hospital’s deficiencies—

(A) immediately jeopardize the health and safety of its patients, the Secretary shall terminate such agreement; or

(B) do not immediately jeopardize the health and safety of its patients, the Secretary may terminate such agreement, or provide that no payment will be made under this subchapter with respect to any individual admitted to such hospital after the effective date of the finding, or both.

(2) If a psychiatric hospital, found to have deficiencies described in paragraph (1)(B), has not complied with the requirements of this subchapter—

(A) within 3 months after the date the hospital is found to be out of compliance with such requirements, the Secretary shall provide that no payment will be made under this subchapter with respect to any individual admitted to such hospital after the end of such 3-month period, or

(B) within 6 months after the date the hospital is found to be out of compliance with such requirements, no payment may be made under this subchapter with respect to any individual in the hospital until the Secretary finds that the hospital is in compliance with the requirements of this subchapter.

(j) Enrollment process for providers of services and suppliers

(1) Enrollment process

(A) In general

The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this subchapter. Such process shall include screening of providers and suppliers in accordance with paragraph (2), a provisional period of enhanced oversight in accordance with paragraph (3), disclosure requirements in accordance with paragraph (4), the imposition of temporary enrollment moratoria in accordance with paragraph (5), and the establishment of compliance programs in accordance with paragraph (6).

(B) Deadlines

The Secretary shall establish by regulation procedures under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of Medicare administrative contractors in meeting the deadlines established under this subparagraph.

(C) Consultation before changing provider enrollment forms

The Secretary shall consult with providers of services and suppliers before making
changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this subchapter.

(2) Provider screening

(A) Procedures

Not later than 180 days after March 23, 2010, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under the program under this subchapter, the Medicaid program under subchapter XIX, and the CHIP program under subchapter XXI.

(B) Level of screening

The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier.

Such screening—

(i) shall include a licensure check, which may include such checks across States; and

(ii) may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include—

(I) a criminal background check;

(II) fingerprinting;

(III) unscheduled and unannounced site visits, including preenrollment site visits;

(IV) database checks (including such checks across States); and

(V) such other screening as the Secretary determines appropriate.

(C) Application fees

(i) Institutional providers

Except as provided in clause (ii), the Secretary shall impose a fee on each institutional provider of medical or other items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted under this paragraph in an amount equal to—

(I) for 2010, $500; and

(II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

(ii) Hardship exception; waiver for certain Medicaid providers

The Secretary may, on a case-by-case basis, exempt a provider of medical or other items or services or supplier from the imposition of an application fee under this subparagraph if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may waive the application fee under this subparagraph for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care.

(iii) Use of funds

Amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1320a–7k of this title.

(D) Application and enforcement

(i) New providers of services and suppliers

The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is not enrolled in the program under this subchapter, subchapter XIX, or subchapter XXI as of March 23, 2010, on or after the date that is 1 year after such date.

(ii) Current providers of services and suppliers

The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is enrolled in the program under this subchapter, subchapter XIX, or subchapter XXI as of such date, on or after the date that is 2 years after such date.

(iii) Revalidation of enrollment

Effective beginning on the date that is 180 days after such date, the screening under this paragraph shall apply with respect to the revalidation of enrollment of a provider of medical or other items or services or supplier in the program under this subchapter, subchapter XIX, or subchapter XXI.

(iv) Limitation on enrollment and revalidation of enrollment

In no case may a provider of medical or other items or services or supplier who has not been screened under this paragraph be initially enrolled or reenrolled in the program under this subchapter, subchapter XIX, or subchapter XXI on or after the date that is 3 years after such date.

(E) Use of information from the Department of Treasury concerning tax debts

In reviewing the application of a provider of services or supplier to enroll or reenroll under the program under this subchapter, the Secretary shall take into account the information supplied by the Secretary of the Treasury pursuant to section 6103(l)(22) of the Internal Revenue Code of 1986, in determining whether to deny such application or to apply enhanced oversight to such provider of services or supplier pursuant to paragraph (3) if the Secretary determines such provider of services or supplier owes such a debt.

(F) Expedited rulemaking

The Secretary may promulgate an interim final rule to carry out this paragraph.
(3) Provisional period of enhanced oversight for new providers of services and suppliers

(A) In general

The Secretary shall establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, as the Secretary determines appropriate, including categories of providers or suppliers, would be subject to enhanced oversight, such as prepayment review and payment caps, under the program under this subchapter, the Medicaid program under subchapter XIX, and the CHIP program under subchapter XXI.

(B) Implementation

The Secretary may establish by program instruction or otherwise the procedures under this paragraph.

(4) 90-day period of enhanced oversight for initial claims of DME suppliers

For periods beginning after January 1, 2011, if the Secretary determines that there is a significant risk of fraudulent activity among suppliers of durable medical equipment, in the case of a supplier of durable medical equipment who is within a category or geographic area under this subchapter identified pursuant to such determination and who is initially enrolling under such subchapter, the Secretary shall, notwithstanding sections 1395h(c), 1395u(c), and 1395ff(a)(2) of this title, withhold payment under such subchapter with respect to durable medical equipment furnished by such supplier during the 90-day period beginning on the date of the first submission of a claim under such subchapter for durable medical equipment furnished by such supplier.

(5) Increased disclosure requirements

(A) Disclosure

A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this subchapter, subchapter XIX, or subchapter XXI on or after the date that is 1 year after March 23, 2010, shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program (as defined in section 1320a–7b(f) of this title), has been excluded from participation under the program under this subchapter, the Medicaid program under subchapter XIX, the Medicare program under subchapter XIX, or has had its billing privileges denied or revoked.

(B) Authority to deny enrollment

If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph (7).

(6) Authority to adjust payments of providers of services and suppliers with the same tax identification number for medicare obligations

(A) In general

Notwithstanding any other provision of this subchapter, in the case of an applicable provider of services or supplier, the Secretary may make any necessary adjustments to payments to the applicable provider of services or supplier under this subchapter in order to satisfy any amount described in subparagraph (B)(ii) due from such obligated provider of services or supplier.

(B) Definitions

In this paragraph:

(i) In general

The term “applicable provider of services or supplier” means a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated provider of services or supplier under such program, regardless of whether the applicable provider of services or supplier is assigned a different billing number or national provider identification number under the program under this subchapter than is assigned to the obligated provider of services or supplier.

(ii) Obligated provider of services or supplier

The term “obligated provider of services or supplier” means a provider of services or supplier that owes an amount that is more than the amount required to be paid under the program under this subchapter (as determined by the Secretary).

(7) Temporary moratorium on enrollment of new providers

(A) In general

The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, including categories of providers of services and suppliers, in the program under this subchapter, under the Medicaid program under subchapter XIX, or under the CHIP program under subchapter XXI if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.

(B) Limitation on review

There shall be no judicial review under section 1395f of this title, section 1395oo of this title, or otherwise, of a temporary moratorium imposed under subparagraph (A).

(8) Compliance programs

(A) In general

On or after the date of implementation determined by the Secretary under subpara-
graph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this subchapter, subchapter XIX, or subchapter XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.

(B) Establishment of core elements

The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.

(C) Timeline for implementation

The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.

(8) Hearing rights in cases of denial or non-renewal

A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this subchapter is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) of this section to a provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this subchapter is denied.

(k) Quality reporting by cancer hospitals

(1) In general

For purposes of fiscal year 2014 and each subsequent fiscal year, a hospital described in section 1395ww(d)(1)(B)(v) of this title shall submit data to the Secretary in accordance with paragraph (2) with respect to such a fiscal year.

(2) Submission of quality data

For fiscal year 2014 and each subsequent fiscal year, each hospital described in such section shall submit to the Secretary data on quality measures specified under paragraph (3). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(3) Quality measures

(A) In general

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

(B) 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 1395aa(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.

(C) Time frame

Not later than October 1, 2012, the Secretary shall publish the measures selected under this paragraph that will be applicable with respect to fiscal year 2014.

(4) Public availability of data submitted

The Secretary shall establish procedures for making data submitted under paragraph (4) available to the public. Such procedures shall ensure that a hospital described in section 1395ww(d)(1)(B)(v) of this title has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients' perspective on care, efficiency, and costs of care that relate to services furnished in such hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

2008—Subsec. (a)(1)(J). Pub. L. 110–276 substituted "section through the operation of subsection (g) or (ll)(2) of section 1395x(t) for "section through the operation of section 1395x(t)" in two places, substituted "defined", for "defined or", and inserted "(and, (through the operation of section 1395x(ll)(2) of this title) with respect to the furnishing of outpatient speech-language pathology" before "before" and "and".


Subsec. (a)(1)(O). Pub. L. 108–173, § 296(a)(1), substituted subpar. (O) for (V) and (V) for (O).


Subsec. (h)(1). Pub. L. 108–173, § 932(b), (c)(1), designated existing provisions as subpar. (A) and added subpars. (B) and (C).


1994—Subsec. (a)(1)(H). Pub. L. 103–432, § 147(e)(7), substituted "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(ii) of this title" for "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(ii) of this title for which payment is made under part B of this subchapter under section 1395m(k) of this title, clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1395l(t)(5) of this title,".


Subsec. (f)(2)(E). Pub. L. 103–162, § 4922(d)(2), inserted "or a Medicare+Choice organization" after "section 1395x(s)(10)(A) of this title".


Subsec. (h)(1). Pub. L. 104–191, § 247(e)(7), substituted "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(ii) of this title" for "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(ii) of this title for which payment is made under part B of this subchapter under section 1395m(k) of this title, clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1395l(t)(5) of this title,".


1994—Subsec. (a)(1)(H). Pub. L. 103–432, § 147(e)(7), substituted "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(ii) of this title" for "section 1395x(s)(2)(K)(i) or 1395x(s)(2)(K)(ii) of this title for which payment is made under part B of this subchapter under section 1395m(k) of this title, clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1395l(t)(5) of this title,".

Subsec. (a)(2)(A). Pub. L. 103–432, § 156(a)(2)(E), struck out "", with respect to items and services furnished in connection with obtaining a second opinion required under section 1320c–13(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion)," after "section 1395x(s)(10)(A) of this title".


Pub. L. 102–54 substituted “Secretary of Veterans Affairs” for “Administrator of Veterans Affairs”.


Sub. (a)(1)(G)(ii). Pub. L. 101–508, § 4157(c), substituted “services described by section 1395dd of this title, certified nurse-midwife services, qualified psychologist services, and” after “and other than”.

Subsec. (a)(1)(I). Pub. L. 101–508, § 4008(b)(3)(B), inserted “and to meet the requirements of such section after “section 1395dd of this title”.


Subsec. (e). Pub. L. 101–508, § 4162(b)(2), substituted “include” and pars. (1) and (2) for “include a clinic, rehabilitation agency, or public health agency if, in the case of a clinic or rehabilitation agency, such clinic or agency meets the requirements of section 1395x(p)(4)(A) or (B) of this title (or meets the requirements of such section through the operation of section 1395x(g) of this title),”.

Subsec. (a)(1)(H). Pub. L. 101–508, § 4157(c)(2), inserted “services described by section 1395x(dd) of this title, certified nurse-midwife services, qualified psychologist services, and” after “and other than”.

Subsec. (a)(1)(I). Pub. L. 101–508, § 4008(b)(3)(B), inserted “and to meet the requirements of such section after “section 1395dd of this title”.


Subsec. (g). Pub. L. 100–485, § 608(d)(19)(A), struck out “and” at end.

Subsec. (a)(1)(O). Pub. L. 100–360, § 411(c)(2)(A)(i), substituted (3) and (4) for “(1) and (2)” for “(3) and (4)” in first sentence.


Subsec. (a)(1)(H). Pub. L. 101–234, § 101(a), repealed Pub. L. 100–360, § 104(d)(5), 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.

managing employee (as defined in section 1320a–5(b) of this title) of such provider, is a person described in section 1320a–3(a) of this title.

Subsec. (a)(3)(C)(II). Pub. L. 100–203, § 4097(b), amended Pub. L. 100–369, § 411(j)(5), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: ‘‘shall not be less in the aggregate for hospitals, facilities, and agencies for a fiscal year than the amount the Secretary determines to be sufficient to cover the costs of such organizations’’ conducting the activities described in subparagraph (a) with respect to such hospitals, facilities, or agencies under part B of subchapter XI of this chapter.’’


Subsec. (b). Pub. L. 100–93, § 8(d)(2), amended subsec. (b) generally, substituting pars. (1) to (3) for former pars. (1) to (3).

Subsec. (c)(1). Pub. L. 100–93, §§ 8(d)(3), (4), substituted ‘‘the Secretary has terminated or has refused to renew an agreement under this subchapter with a provider of services’’ for ‘‘an agreement filed under this subchapter by a provider of services has been terminated by the Secretary’’ and inserted ‘‘or nonrenewal’’ after ‘‘termination’’.

Subsec. (c)(2). Pub. L. 100–203, § 4212(e)(4), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: ‘‘In the case of a skilled nursing facility participating in the programs established by this subchapter and subchapter XIX of this chapter, the Secretary may enter into an agreement under this section only if such facility has been approved pursuant to section 1396a(e)(1) of this title, and the term of any such agreement shall be in accordance with the period of approval of eligibility specified by the Secretary pursuant to such section.’’

Subsec. (c)(3). Pub. L. 100–203, § 4212(e)(4), redesignated par. (3) as (2).

Pub. L. 100–93, §§ 8(d)(3), (4), substituted ‘‘the Secretary has terminated or has refused to renew an agreement under this subchapter with a provider of services’’ for ‘‘an agreement filed under this subchapter by a provider of services has been terminated by the Secretary’’ and inserted ‘‘or nonrenewal’’ after ‘‘termination’’.

Pub. L. 100–369, § 411(j)(4)(C)(vi), substituted ‘‘money penalty’’ for ‘‘monetary penalty’’ in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: ‘‘Such a penalty shall be imposed in the same manner as civil monetary penalties are imposed under section 1320a–7a of this title with respect to actions described in subsection (a)(3) of that section.’’

Pub. L. 100–203, § 4085(x)(17), substituted ‘‘inconsistent with an arrangement under subsection (a)(1)(H) of this section in violation of the requirement for such an arrangement’’ for ‘‘for a hospital outpatient patient service for which payment may be made under part B of this subchapter and such bill or request violates an arrangement under subsection (a)(1)(H) of this section’’.

Subsec. (b). Pub. L. 100–93, § 8(d)(5), added subsec. (b). 1986—Subsec. (a)(1)(F). Pub. L. 99–509, § 9333(e)(1)(A), designated existing provisions as cl. (i) and in cl. (i), as so redesignated, redesignated former cls. (i) to (iii) as subcls. (I) to (III), and added cl. (i).

Pub. L. 99–272, § 9402(a), redesignated cl. (iv) as (iii) and in cl. (i), as so redesignated, substituted ‘‘1986’’ for ‘‘1982’’ and struck out former cl. (iii) which provided that the cost of such agreement to the hospital shall not be less than amount which reflects the rates previously established in fiscal year 1982 for both direct and administrative costs (adjusted for inflation).

Subsec. (a)(1)(H). Pub. L. 99–509, § 9333(c)(2), struck out ‘‘inpatient hospital’’ after ‘‘hospitals which provide’’ and substituted ‘‘patient’’ for ‘‘an inpatient’’.

Pub. L. 99–93, § 9230(c)(2), inserted ‘‘, and other than services of a certified registered nurse anesthetist’’ after ‘‘section 1395x(a)(14) of this title’’.


Pub. L. 99–272, § 9402(b), added subpar. (l) relating to agreement not to charge for certain items or services.

Pub. L. 99–272, § 9121(a), added subpar. (J) relating to compliance with the requirements of section 1395dd of this title.

Subsec. (a)(1)(K). Pub. L. 99–514 redesignated subpar. (1) relating to agreement not to charge for certain items and services as subpar. (K).


Subsec. (a)(2)(A). Pub. L. 99–272, § 9401(b)(2)(F), inserted ‘‘, with respect to items and services furnished in connection with obtaining a second opinion required under section 1320―19(c)(2) of this title (or a third opinion, if the second opinion was in disagreement with the first opinion),’’ after ‘‘1395x(s)(10)(A) of this title’’ in last sentence.


Subsec. (e). Pub. L. 99–509, § 9337(c)(2), inserted in second sentence ‘‘(or meets the requirements of such section through the operation of section 1395x(g) of this title)’’ in two places, and inserted ‘‘or (through the operation of section 1395x(g) of this title) with respect to the furnishing of outpatient occupational therapy services’’ after ‘‘as therein defined’’.


Subsec. (a)(1)(F). Pub. L. 98–369, § 2315(d), substituted ‘‘(b), (c), or (d)’’ for ‘‘(c) or (d)’’.

Pub. L. 98–369, § 2347(a)(1), substituted ‘‘maintain an agreement with a professional standards review organization (if there is such an organization in existence in the area in which the hospital is located) or with a utilization and quality control peer review organization which has a contract with the Secretary under part B of subchapter XI of this chapter for the area in which the hospital is located, under which the organization for ‘‘maintain an agreement with a utilization and quality control peer review organization (if there is such an organization which has a contract with the Secretary under part B of subchapter XI of this chapter for the area in which the hospital is located) under which the organization’’.


Subsec. (a)(2)(A). Pub. L. 98–369, § 2369(f), inserted ‘‘and with respect to clinical diagnostic laboratory tests’’ after ‘‘section 1395x(s)(10) of this title’’.

Pub. L. 98–369, § 2321(c), inserted ‘‘or which are durable medical equipment furnished as home health services’’ after ‘‘part B of this subchapter’’.

Pub. L. 98–369, § 2332(b)(3), substituted ‘‘section 1395x(s)(10)(A) of this title’’ for ‘‘section 1395x(s)(10) of this title’’.

Subsec. (b)(3). Pub. L. 98–369, § 2335(d)(1), substituted ‘‘(including inpatient psychiatric hospital services)’’ for ‘‘(including tuberculosis hospital services and inpatient psychiatric hospital services)’’.

Pub. L. 98–369, § 2354(b)(34), realigned margin of par. (3).

Subsec. (b)(4). Pub. L. 98–369, § 2348(a), substituted ‘‘more than 30 days after such effective date’’ for ‘‘after the calendar year in which such termination is effective’’.

Subsec. (d). Pub. L. 98–369, § 2335(d)(2), substituted ‘‘(including inpatient psychiatric hospital services)’’ for ‘‘(including inpatient tuberculosis hospital services and inpatient psychiatric hospital services)’’.

1983—Subsec. (a)(1). Pub. L. 98–21, § 602(c)(2), inserted provision at end of par. (1) that in the case of a hospital which has an agreement in effect with an organization.
described in subparagraph (F), which organization’s contract with the Secretary under part B of subchapter XI terminates on or after October 1, 1984, the hospital shall be determined to be out of compliance with the requirement of such subparagraph during the six month period beginning on the date of the termination of that contract.

Subsec. (a)(1)(F). Pub. L. 98–21, § 602(j)(1), which provided that, effective Oct. 1, 1984, subpar. (F) is amended by substituting "with an organization" for "if there is such an organization", was repealed by Pub. L. 98–508, § 1247(a), effective July 18, 1984.

Subsec. (a)(1)(F) to (H). Pub. L. 98–21, § 602(c)(1), added subpars. (F) to (H).


Subsec. (a)(2)(B)(ii). Pub. L. 98–21, § 602(d)(2), inserted and except with respect to inpatient hospital costs with respect to which amounts are payable under section 1395ww(d) of this title after "except with respect to emergency services" in provision preceding subj. (L).


Subsec. (b). Pub. L. 97–248, § 128(a)(6), in provisions preceding par. (1), struck out "(and in the case of a skilled nursing facility, prior to the end of the term specified in subsection (a)(1) of this section)" after "may be terminated".

Subsec. (h)(4)(A). Pub. L. 97–448, § 128(g)(6), inserted "or hospice care" after "home health services".

1981—Subsec. (a)(1). Pub. L. 97–35 struck out provision following subpar. (D) which provided that an agreement with a skilled nursing facility be for a term not exceeding 12 months with the exception that the Secretary could extend the time in specified situations.

1980—Subsec. (a)(2)(A). Pub. L. 96–611 inserted provision that a provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1396a(e)(10) of this title for which payment is made under part B of this subchapter.


1979—Subsec. (a)(2)(A). Pub. L. 95–292 provided for computation of and charging of coinsurance amounts for items and services furnished individuals with end stage renal disease on the basis established by the Secretary.


Subsec. (b)(2)(C). Pub. L. 95–142, § 3(b), designated existing provisions as subcl. (i) and added subcl. (ii).

Subsec. (b)(2)(F). Pub. L. 95–142, § 13(b)(3), substituted "of a quality which fails to meet professionally recognized standards of health care" for "harmful to individuals or to be of a grossly inferior quality", and struck out provisions relating to approval by an appropriate program review team.

Subsec. (c)(2). Pub. L. 95–210 substituted "section 1396a(a) of this title" for "section 1396i of this title".

1972—Subsec. (a)(1). Pub. L. 92–603, §§ 227(d)(2), 229(a)(17), 278(a)(17), (b)(18), 281(c), substituted "Any provider of services (except a fund designated for purposes of section 1395f(g) and section 1395e(e) of this title)" for "Any provider of services; 'skilled nursing facility' for 'extended care facility'; and the agreement be for a term of not to exceed 12 months with an allowable extension of 2 months under specified circumstances, redesignated subpar. (B) as (C) and added subpar. (B).

Subsec. (a)(2)(B). Pub. L. 92–603, § 228(e), designated existing provisions as cl. (I) and added cl. (II).

Subsec. (a)(2)(C). Pub. L. 92–603, § 229(g)(2), substituted "this subparagraph" for "clause (iii) of the preceding sentence".


Subsec. (b). Pub. L. 92–603, §§ 229(b), 249(a), 278(a)(17), inserted "(and in the case of an extended care facility, prior to the end of the term specified in subsection (a)(1) of this section)" in provision preceding par. (1), in par. (2), added cls. (D) to (F), and in par. (3), substituted "(including tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services, with respect to services furnished after the effective date of such termination, except that payment may be made for up to thirty days with respect to inpatient institutional services furnished to any eligible individual who was admitted to such institution prior to" for "(including inpatient tuberculosis hospital services and inpatient psychiatric hospital services) or post-hospital extended care services, with respect to such services furnished to any individual who is admitted to the hospital or extended care facility furnishing such services on or after" and substituted "skilled nursing facility" for "extended care facility".

Subsec. (c). Pub. L. 92–603, § 249(a)(d), designated existing provisions as par. (1) and added par. (2).

Subsec. (d). Pub. L. 92–603, § 278(a)(17), substituted "skilled nursing facility" for "extended care facility" and "a" for "an".

1968—Subsec. (a)(2)(A). Pub. L. 90–248, § 129(c)(12)(A)(i), (ii), substituted "or (a)(3)" for ", (a)(2), or (a)(4)" in cl. (I), and deleted "or, in the case of outpatient hospital diagnostic services, for which payment is made under part A" in cl. (II).


Pub. L. 90–248, § 135(b), authorized a provider of services to charge for blood in accordance with its customary practices, included, in addition to whole blood for which a provider of services may charge, equivalent quantities of packed red blood cells, and provided that blood furnished an individual will be deemed replaced when the provider is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells) furnished the individual to which the three pint deductible applies.

Subsec. (e). Pub. L. 90–248, § 133(c), added subsec. (e).

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 110–148, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by section 6406(b) of Pub. L. 111–148 applicable to orders, certifications, and referrals made on or after Jan. 1, 2010, see section 6406(d) of Pub. L. 111–148, set out as a note under section 1395w–2 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–275 applicable to services furnished on or after July 1, 2009, see section 1395gg of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–173, title II, §§ 236(c), Dec. 8, 2003, 117 Stat. 2212, provided that: "The amendments made by this section (amending this section and sections 1395ee, 1396a, and 1396a–4 of this title) shall apply to services furnished on or after January 1, 2004."
Amendment by section 505(b) of Pub. L. 108–173 first applicable to the wage index for discharges occurring on or after Oct. 1, 2004, see section 505(c) of Pub. L. 108–173, set out as a note under section 1385w of this title.

Pub. L. 108–173, title V, §506(b), Dec. 8, 2003, 117 Stat. 2265, provided that: "The amendments made by this section [amending this section] shall apply as of a date specified by the Secretary of Health and Human Services (but in no case later than 1 year after the date of enactment of this Act (Dec. 8, 2003)) to Medicare participation agreements in effect (or entered into) on or after such date."

Amendment by section 932(b), (c)(1) of Pub. L. 108–173 applicable to appeals filed on or after Oct. 1, 2004, see section 932(d) of Pub. L. 108–173, set out as a note under section 1385i–3 of this title.


"(1) ENROLLMENT PROCESS.—The Secretary [of Health and Human Services] shall provide for the establishment of the enrollment process under section 1866(h)(1) of the Social Security Act [subsection (j)(1) of this section], as added by subsection (a)(2), within 6 months after the date of the enactment of this Act [Dec. 8, 2003].

(2) CONSULTATION.—Section 1866(h)(2) of the Social Security Act [former subsection (j)(2), now subsection (j)(8), of this section], as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(h)(2) of the Social Security Act [former subsection (j)(2), now subsection (j)(8), of this section], as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003]) as the Secretary specifies."


**Effective Date of 2000 Amendment**

Amendment by Pub. L. 106–554 applicable to services furnished on or after Jan. 1, 2001, see section 1a(a)(6) (title III, §313(c)) of Pub. L. 106–554, set out as a note under section 1395u of this title.

**Effective Date of 1999 Amendment**


**Effective Date of 1997 Amendments**

Amendment by Pub. L. 105–12 effective Apr. 30, 1997, and applicable to Federal payments made pursuant to obligations incurred after Apr. 30, 1997, for items and services provided on or after such date, subject to also being applicable with respect to contracts entered into, renewed, or extended after Apr. 30, 1997, as well as contracts entered into before Apr. 30, 1997, to the extent permitted under such contracts, see section 11 of Pub. L. 105–12, set out as an Effective Date note under section 14401 of this title.

Amendment by section 4201(c)(1) 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.

Amendment by section 4302(a) of Pub. L. 105–33 effective Aug. 5, 1997, and applicable to the entry and renewal of contracts on or after such date, see section 4302(c) of Pub. L. 105–33, set out as a note under section 1395u of this title.

Amendment by section 4232(b) of Pub. L. 105–33 effective as of date specified by Secretary of Health and Human Services in regulations to be issued by Secretary not later than date which is one year after Aug. 5, 1997, see section 4232(d)(2) of Pub. L. 105–33, set out as an Effective Date note under section 1320b–16 of this title.

Amendment by section 4432(b)(5) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1998, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395i–3 of this title.

Amendment by section 4511(a)(2)(D) of Pub. L. 105–33 applicable with respect 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 4514(a)(3) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1999, see section 4514(e) of Pub. L. 105–33, set out as a note under section 1395j of this title.

Section 461(b) of Pub. L. 105–33 provided that: "The amendment made by subsection (a) [amending this section] shall apply to provider agreements entered into, renewed, or extended on or after such date (not later than 1 year after the date of the enactment of this Act [Aug. 5, 1997]) as the Secretary of Health and Human Services specifies."

Amendments by section 4714(b)(1) of Pub. L. 105–33 applicable to payment for (and with respect to provider agreements with respect to) items and services furnished on or after Aug. 5, 1997, see section 4714(c) of Pub. L. 105–33, set out as a note under section 1396a of this title.

**Effective Date of 1994 Amendments**

Section 106(b)(2) of Pub. L. 103–432 provided that: "The amendments made by paragraph (1) [amending this section and section 1395f of this title] shall take effect as if included in the enactment of OBRA–1987 [Pub. L. 100–203]."

Amendment by section 147(e)(7) of Pub. L. 103–432 as if included in the enactment of Pub. L. 103–432, set out as a note under section 1320a–3 of this title.

Amendment by section 156(a)(2)(E) of Pub. L. 103–432 applicable to services provided on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103–432, set out as a note under section 1320c–3 of this title.


**Effective Date of 1990 Amendment**

Section 400(b)(4) of Pub. L. 101–508 provided that: "The amendments made by this subsection [amending this section and section 1395dd of this title] shall apply to actions occurring on or after the first day of the sixth month beginning after the date of the enactment of this Act [Nov. 5, 1990]."


Amendment by section 4157(c)(2) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4157(d) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4162(b)(2) 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.

**Effective Date of 1989 Amendments**

Section 601(b) of Pub. L. 101–239 provided that: "The amendments made by subsection (a) [amending this
section] shall take effect on the first day of the first month that begins more than 180 days after the date of the enactment of this Act [Dec. 19, 1988], without regard to whether regulations to carry out such amendments have been promulgated by such date."

Amendment by section 6112(e)(3) of Pub. L. 101–239 applicable with respect to items furnished on or after Jan. 1, 1989, see section 6112(f)(4) of Pub. L. 101–239, set out as a note under section 1395m of this title.


Amendment by section 201(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1323b–7a of this title.

**Effective Date of 1988 Amendments**


Amendment by section 104(d)(5) of Pub. L. 100–360 effective Jan. 1, 1989, except as otherwise provided, and applicable to inpatient hospital deductible for 1989 and succeeding years, to care and services furnished on or after Jan. 1, 1989, to premiums for January 1989 and succeeding months, and to blood or blood cells furnished on or after Jan. 1, 1989, see section 104(a) of Pub. L. 100–360, set out as a note under section 1395d of this title.

Amendment by section 202(b)(1) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(g)(1) of Pub. L. 100–994, set out as a note under section 1395u of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(c)(2)(C), (g)(1)(D), (l)(4)(C)(vi), (j)(5) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1985, Pub. L. 99–272, set out as a note under section 1395m of this title.

The amendment made by this section [amending this section] shall apply to admissions occurring on or after Apr. 1, 1988, or, if later, the earliest date the Secretary can provide applicable to admissions occurring on or after Apr. 1, 1988, set out as a note under section 1395m of this title.

Section 4085(i)(17) of Pub. L. 100–203 provided that: "The amendments made by clause (i) [amending this section] shall apply to inpatient hospital services furnished on or after Jan. 1, 1989." Amendment by section 293(b) of Pub. L. 99–509 provided that: "The amendments made by subsection (a) [amending this section] shall apply to inpatient hospital services furnished on or after Jan. 1, 1989." Amendment by Pub. L. 99–514 effective, except as otherwise provided, as if included in enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99–272, set out as a note under section 1320a–7 of Title 42, Internal Revenue Code.

**Effective Date of 1986 Amendments**

Amendment by section 6112(e)(3) of Pub. L. 101–239 applicable to admissions occurring on or after Jan. 1, 1990, see section 6112(f)(4) of Pub. L. 101–239, set out as a note under section 1395m of this title.

Amendment by section 608(d)(3)(F), (19)(A) of Pub. L. 101–239 applicable with respect to items furnished on or after Jan. 1, 1990, see section 608(c)(1), (2) of Pub. L. 101–239, set out as a note under section 704 of this title.

Amendment by section 104(d)(5) of Pub. L. 101–239 effective Jan. 1, 1990, except as otherwise provided, and applicable to services furnished after June 30, 1990, see section 104(a) of Pub. L. 101–239, set out as a note under section 1395d of this title.

Amendment by section 202(b)(1) of Pub. L. 101–239 applicable to items dispensed on or after Jan. 1, 1990, see section 202(g)(1) of Pub. L. 100–994, set out as a note under section 1395u of this title.

Except as specifically provided in section 411 of Pub. L. 101–239, amendment by section 411(c)(2)(C), (g)(1)(D), (l)(4)(C)(vi), (j)(5) of Pub. L. 101–239, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Section 411(c)(2)(A)(ii) of Pub. L. 100–360 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to agreements under section 1395k of this title.

Amendment by section 4085(i)(17) of Pub. L. 100–203 applicable to covered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4086(e) of Pub. L. 100–203, as amended, set out as a note under section 1395f of this title.

Amendment by section 4085(i)(17) of Pub. L. 100–203 provided that the amendment made by such section 4085(i)(17) is effective as if included in the enactment of Pub. L. 99–509.

Section 4097(c) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section] shall apply with respect to fiscal years beginning on or after October 1, 1988."

Amendment by section 4212(e)(4) of Pub. L. 100–203 applicable to nursing facility services furnished on or after Oct. 1, 1990, without regard to whether regulations implementing such amendment are promulgated by such date, except as otherwise specifically provided in section 1396r of this title, with transitional rule, see section 4212(a), (b)(2) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1396r of this title.

Amendment by Pub. L. 100–93 effective at end of fourteen-year period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 105(a)(1) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

**Effective Date of 1984 Amendment**

Amendment by section 2303(f) of Pub. L. 98–369 applicable to clinical diagnostic laboratory tests furnished...
on or after July 1, 1984, but not applicable to clinical diagnostic laboratory tests furnished to inpatients of a provider operating under a waiver granted pursuant to section 1395(e) of Pub. L. 98–21, set out as a note under section 1395y of this title, see section 2303(c)(1), (3) of Pub. L. 98–369, set out as a note under section 1395y of this title.

Amendment by section 2315(d) of Pub. L. 98–369 effective as though included in the enactment of the Social Security Amendments of 1983, Pub. L. 98–21, see section 2315(g) of Pub. L. 98–369, set out as Effective and Termination Dates of 1984 Amendment note under section 1395w of this title.

Amendment by section 2321(c) 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 1395y of this title.

Amendment by section 2323(b)(3) of Pub. L. 98–369 applicable to services furnished on or after Sept. 1, 1984, see section 2323(d) of Pub. L. 98–369, set out as a note under section 1395y of this title.

Amendment by section 2335(d) of Pub. L. 98–369 effective July 18, 1984, see section 2335(g) of Pub. L. 98–369, set out as a note under section 1395y of this title.

Amendment by section 2347(a) of Pub. L. 98–369 effective July 18, 1984, see section 2347(d) of Pub. L. 98–369, set out as a note under section 1395y of this title.

Section 2348(b) of Pub. L. 98–369 provided that: "The amendment made by this section [amending this section] shall apply to terminations issued on or after the date of the enactment of this Act (July 18, 1984)."

Amendment by section 2354(b)(35), (34) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed under the provisions of law involved before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1983 Amendments**


Amendment by section 602(f)(2) 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 602(f)(3) of Pub. L. 98–369, set out as a note under section 1395w of this title.

Subsec. (a)(1)(F) to (H) of this section, as added by section 602(h)(1)(C) of Pub. L. 98–21, effective Oct. 1, 1983, see section 604(a)(2) of Pub. L. 98–21, set out as a note under section 1395w of this title.

Amendment by section 309(a)(5) of Pub. L. 97–448 effective as if originally included in the provision of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, to which such amendment relates, see section 309(c)(1) of Pub. L. 97–448, set out as a note under section 426 of this title.

Amendment by section 309(b)(1) of Pub. L. 97–448 effective as if originally included as a part of this section as this section was amended by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, to which amendment relates, see section 309(c)(1) of Pub. L. 97–448, set out as a note under section 426 of this title.

**Effective Date of 1982 Amendment**

Amendment by section 122(e)(5), (6) 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 1385c of this title.

Amendment by section 128(c)(6) of Pub. L. 97–248 effective as if originally included as a part of this section as this section was amended by the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, see section 128(c)(2) of Pub. L. 97–248, set out as a note under section 1396x of this title.


Amendment by section 144 of Pub. L. 97–248 effective with respect to contracts entered into or renewed on or after Sept. 3, 1992, see section 149 of Pub. L. 97–248, set out as an Effective Date note under section 1323c of this title.

**Effective Date of 1980 Amendment**

Amendment by Pub. L. 96–611 effective July 1, 1981, and applicable to services furnished on or after that date, see section 2 of Pub. L. 96–611, set out as a note under section 1395y of this title.

**Effective Date of 1978 Amendment**

Amendment by Pub. L. 95–292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility's or provider's first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as a note under section 426 of this title.

**Effective Date of 1977 Amendments**

Section 2(f) of Pub. L. 95–210 provided that:

"(1) The amendments made by this section [amending this section and sections 1369a, 1369d, and 1396i of this title] shall (except as otherwise provided in paragraph (2)) apply to medical assistance provided under a State plan approved under title XIX of the Social Security Act [subchapter XIX of this chapter], and on and after the first day of the first calendar quarter that begins more than six months after the date of enactment of this Act [Dec. 13, 1977]." "(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act [subchapter XIX of this chapter] which the Secretary determines requires State legislation in order for the plan to meet the additional requirements imposed by the amendments made by this section, the State plan shall not be regarded as failing to comply with the requirements of such title [subchapter] solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act [Dec. 13, 1977]."

Amendment by section 3(b) of Pub. L. 95–142 effective Oct. 25, 1977, see section 3(e) of Pub. L. 95–142, set out as an Effective Date note under section 1320a–3 of this title.

Amendment by section 8(b) of Pub. L. 95–142 [amending this section] applicable with respect to contracts, agreements, etc., made on and after first day of fourth month beginning after Oct. 25, 1977, see section 8(e) of Pub. L. 95–142, set out as an Effective Date note under section 1320a–3 of this title.

Amendment by section 13(b)(3) of Pub. L. 95–142 effective Oct. 25, 1977, see section 13(c) of Pub. L. 95–142, set out as a note under section 1395y of this title.

Section 15(b) of Pub. L. 95–142 provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to agreements entered into or renewed on and after the date of enactment of this Act [Oct. 25, 1977]."

**Effective Date of 1972 Amendment**

Amendment by section 223(e), (g) of Pub. L. 92–603 effective with respect to accounts of a facility's or provider's first accounting period beginning after Dec. 31, 1972, see section 223(h) of Pub. L. 92–603, set out as a note under section 1385x of this title.
Amendment by section 227(d)(2) of Pub. L. 92–603 applicable with respect to accounting periods beginning after June 30, 1973, see section 227(g) of Pub. L. 92–603, set out as a note under section 1395x of this title.

Section 249A(e) of Pub. L. 92–603 provided that: ‘‘The provisions of this section [enacting section 1396 of this title and amending this section] shall be effective with respect to agreements filed with the Secretary under section 1386 of the Social Security Act [this section] by skilled nursing facilities (as defined in section 1381(d) of such Act [section 1381x(d)] of this title) before, on, or after the date of enactment of this Act [Oct. 30, 1972], but accepted by him on or after such date.’’

Amendment by section 281(c) of Pub. L. 92–603 applicable in the case of notices sent to individuals after 1968, see section 281(g) of Pub. L. 92–603, set out as a note under section 1395gs of this title.

Effective Date of 1968 Amendment

Amendment by section 128(c)(12) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 129(d) of Pub. L. 90–248, set out as a note under section 1395x of this title.

Amendment by section 133(c) of Pub. L. 90–248 applicable with respect to services furnished after June 30, 1968, see section 133(g) of Pub. L. 90–248, set out as a note under section 1395x of this title.

Amendment by section 136(b) of Pub. L. 90–248 applicable with respect to payment for blood (or packed red blood cells) furnished an individual after Dec. 31, 1967, see section 136(d) of Pub. L. 90–248, set out as a note under section 1395x of this title.

Regulations

Pub. L. 108–173, title V, § 506(c), Dec. 8, 2003, 117 Stat. 2295, provided that: ‘‘The Secretary [of Health and Human Services] shall promulgate regulations to carry out the amendments made by subsection (a) [amending this section].’’

Disclosure of Medicare Terminated Providers and Suppliers to States

Pub. L. 111–118, title VI, § 610(b)(2), Mar. 23, 2010, 124 Stat. 752, provided that: ‘‘The Administrator of the Centers for Medicare & Medicaid Services shall establish a process for making available to the each [sic] State agency with responsibility for administering a State Medicaid plan (or a waiver of such plan) under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) or a child health plan under title XXI [42 U.S.C. 1396a et seq.] the name, national provider identifier, and other identifying information for any provider of medical or other items or services or supplier under the Medicare program under title XVIII [42 U.S.C. 1395 et seq.] or under the CHIP program under title XXI that is terminated from participation under that program within 30 days of the termination (and, with respect to all such providers or suppliers who are terminated from the Medicare program on the date of enactment of this Act [Mar. 23, 2010], within 90 days of such date).’’

Office of the Inspector General, Report on Compliance With and Enforcement of National Standards on Culturally and Linguistically Appropriate Services (CLAS) in Medicare


‘‘(1) In general.—The Comptroller General of the United States shall conduct a study on concierge care (as defined in paragraph (2)) to determine the extent to which such care—

‘‘(A) is used by Medicare beneficiaries (as defined in section 1802(b)(5)(A) of the Social Security Act (42 U.S.C. 1395a(b)(5)(A))); and

‘‘(B) has impacted upon the access of Medicare beneficiaries (as so defined) to items and services for which reimbursement is provided under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).’’

‘‘(2) Concierge care.—In this section, the term ‘concierge care’ means an arrangement under which, as a prerequisite for the provision of a health care item or service to an individual, a physician, practitioner (as described in section 1852(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C))), or other individual—

‘‘(A) charges a membership fee or another incidental fee to an individual desiring to receive the health care item or service from such physician, practitioner, or other individual; or

‘‘(B) requires the individual desiring to receive the health care item or service from such physician, practitioner, or other individual to purchase an item or service.

‘‘(b) Report.—Not later than the date that is 12 months after the date of enactment of this Act [Dec. 8, 2003], the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a)(1) together with such recommendations for legislative or administrative action as the Comptroller General determines to be appropriate.’’

Effect on State Law

Section 4206(c) of Pub. L. 101–508 provided that: ‘‘Nothing in subsections (a) and (b) [amending this section and sections 1396i and 1395gg of this title] shall be construed to prohibit the application of a State law which allows for an objection on the basis of conscience for any health care provider or any agent of such provider which, as a matter of conscience, cannot implement an advance directive.’’

Reports to Congress on Number of Hospitals Terminating or Not Renewing Provider Agreements

Section 233(c) of Pub. L. 99–576 provided that: ‘‘(1) The Secretary of Health and Human Services shall periodically submit to the Congress a report on the number of hospitals that have terminated or failed to renew an agreement under section 1866 of the Social Security Act [this section] as a result of the additional conditions imposed under the amendments made by subsection (a) [amending this section].’’

‘‘(2) Not later than October 1, 1987, the Administrator of Veterans’ Affairs shall submit to the Committees on Veterans’ Affairs of the Senate and House of Representatives a report regarding implementation of this section [amending this section]. Thereafter, the Administrator shall notify such committees if any hospital terminates or fails to renew an agreement described in
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paraphrase (1) for the reasons described in that para-

paragraph.”

[For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103–7 (in which item 7 on page 96 identifies a report on “Hospitals that have terminated or failed to renew an agreement under section 1866 of Social Security Act as a result of the additional conditions imposed” authorized by 42 U.S.C. 1395cc note), see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.] Section 9122(d) of Pub. L. 99–272 provided that: “The Secretary of Health and Human Services shall report to Congress periodically on the number of hospitals that have terminated or failed to renew an agreement under section 1866 of the Social Security Act (this section) as a result of the additional conditions imposed under the amendments made by subsection (a) (amending this section).”

[For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103–7 (in which item 7 on page 96 identifies a report on “Hospitals that have terminated or failed to renew an agreement under section 1866 of Social Security Act as a result of the additional conditions imposed” authorized by 42 U.S.C. 1395cc note), see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.]

DELAY IN IMPLEMENTATION OF REQUIREMENT THAT HOSPITALS MAINTAIN AGREEMENTS WITH UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION

Section 2347(b) of Pub. L. 98–369 provided that: “Notwithstanding section 604(a)(2) of the Social Security Amendments of 1983 [section 604(a)(2) of Pub. L. 98–21, set out as an Effective Date of 1983 Amendment note under section 1983w of this title], the requirement that a hospital maintain an agreement with a utilization and quality control peer review organization, as contained in section 1866(a)(1)(F) of the Social Security Act [subsec. (a)(1)(F) of this section], shall become effective on November 15, 1984.”

INTERIM WAIVER IN CERTAIN CASES OF BILLING RULE FOR ITEMS AND SERVICES OTHER THAN PHYSICIANS’ SERVICES

For authority to waive the requirements of subsec. (a)(1)(H) of this section for any cost period prior to Oct. 1, 1986, where immediate compliance would threaten the stability of patient care, see section 602(k) of Pub. L. 98–21, set out as a note under section 1113 of Title 31, Money and Finance.

PRIVATE SECTOR REVIEW INITIATIVE

Section 119 of Pub. L. 97–248 provided that: “(a) The Secretary of Health and Human Services shall undertake an initiative to improve medical review by intermediaries and carriers under title XVIII of the Social Security Act [this subchapter] and to encourage similar review efforts by private insurers and other private entities. The initiative shall include the development of specific standards for measuring the performance of such intermediaries and carriers with respect to the identification and reduction of unnecessary utilization of health services.

“(b) Where such review activity results in the denial of payment to providers of services under title XVIII of the Social Security Act [this subchapter], such providers shall be prohibited, in accordance with sections 1866 and 1879 of such title [this section and section 1395pp of this title], from collecting any payments from beneficiaries unless otherwise provided under such title.”

AGREEMENTS FILED AND ACCEPTED PRIOR TO OCT. 30, 1972, DEEMED TO BE FOR SPECIFIED TERM ENDING DEC. 31, 1973

Section 249A(f) of Pub. L. 92–603 provided that: “Notwithstanding any other provision of law, any agree-

ment, filed by a skilled nursing facility (as defined in section 1861(j) of the Social Security Act [section 1395(i) of this title]) with the Secretary under section 1861 of such Act [this section] and accepted by him prior to the date of enactment of this Act [Oct. 30, 1972], which was in effect on such date shall be deemed to be for a specified term ending on December 31, 1973.”

§ 1395cc–1. Demonstration of application of physician volume increases to group practices

(a) Demonstration program authorized

(1) In general

The Secretary shall conduct demonstration projects to test and, if proven effective, expand the use of incentives to health care groups participating in the program under this subchapter that—

(A) encourage coordination of the care furnished to individuals under the programs under parts A and B of this subchapter by institutional and other providers, practitioners, and suppliers of health care items and services;

(B) encourage investment in administrative structures and processes to ensure efficient service delivery; and

(C) reward physicians for improving health outcomes.

Such projects shall focus on the efficiencies of furnishing health care in a group-practice setting as compared to the efficiencies of furnishing health care in other health care delivery systems.

(2) Administration by contract

Except as otherwise specifically provided, the Secretary may administer the program under this section in accordance with section 1395cc–2 of this title.

(3) Definitions

For purposes of this section, terms have the following meanings:

(A) Physician

Except as the Secretary may otherwise provide, the term “physician” means any individual who furnishes services which may be paid for as physicians’ services under this subchapter.

(B) Health care group

The term “health care group” means a group of physicians (as defined in subparagraph (A)) organized at least in part for the purpose of providing physicians’ services under this subchapter. As the Secretary finds appropriate, a health care group may include a hospital and any other individual or entity furnishing items or services for which payment may be made under this subchapter that is affiliated with the health care group under an arrangement structured so that such individual or entity participates in a demonstration under this section and will share in any bonus earned under subsection (d) of this section.

(b) Eligibility criteria

(1) In general

The Secretary is authorized to establish criteria for health care groups eligible to partici-
pate in a demonstration under this section, including criteria relating to numbers of health care professionals in, and of patients served by, the group, scope of services provided, and quality of care.

(2) Payment method

A health care group participating in the demonstration under this section shall agree with respect to services furnished to beneficiaries within the scope of the demonstration (as determined under subsection (c) of this section)—

(A) to be paid on a fee-for-service basis; and

(B) that payment with respect to all such services furnished by members of the health care group to such beneficiaries shall (where determined appropriate by the Secretary) be made to a single entity.

(3) Data reporting

A health care group participating in a demonstration under this section shall report to the Secretary such data, at such times and in such format as the Secretary requires, for purposes of monitoring and evaluation of the demonstration under this section.

(c) Patients within scope of demonstration

(1) In general

The Secretary shall specify, in accordance with this subsection, the criteria for identifying those patients of a health care group who shall be considered within the scope of the demonstration under this section for purposes of application of subsection (d) of this section and for assessment of the effectiveness of the group in achieving the objectives of this section.

(2) Other criteria

The Secretary may establish additional criteria for inclusion of beneficiaries within a demonstration under this section, which may include frequency of contact with physicians in the group or other factors or criteria that the Secretary finds to be appropriate.

(3) Notice requirements

In the case of each beneficiary determined to be within the scope of a demonstration under this section with respect to a specific health care group, the Secretary shall ensure that such beneficiary is notified of the incentives, and of any waivers of coverage or payment rules, applicable to such group under such demonstration.

(d) Incentives

(1) Performance target

The Secretary shall establish for each health care group participating in a demonstration under this section—

(A) a base expenditure amount, equal to the average total payments under parts A and B of this subchapter for patients served by the health care group on a fee-for-service basis in a base period determined by the Secretary; and

(B) an annual per capita expenditure target for patients determined to be within the scope of the demonstration, reflecting the base expenditure amount adjusted for risk and expected growth rates.

(2) Incentive bonus

The Secretary shall pay to each participating health care group (subject to paragraph (4)) a bonus for each year under the demonstration equal to a portion of the medicare savings realized for such year relative to the performance target.

(3) Additional bonus for process and outcome improvements

At such time as the Secretary has established appropriate criteria based on evidence the Secretary determines to be sufficient, the Secretary shall also pay to a participating health care group (subject to paragraph (4)) an additional bonus for a year, equal to such portion as the Secretary may designate of the saving to the program under this subchapter resulting from process improvements made by and patient outcome improvements attributable to activities of the group.

(4) Limitation

The Secretary shall limit bonus payments under this section as necessary to ensure that the aggregate expenditures under this subchapter (inclusive of bonus payments) with respect to patients within the scope of the demonstration do not exceed the amount which the Secretary estimates the savings resulting from process improvements made by and patient outcome improvements attributable to activities of the group.

Parts A and B of this subchapter, referred to in subsecs. (a)(1)(A) and (d)(1)(A), are classified to sections 1395cc et seq. and 1395j et seq., respectively, of this title.

GAO REPORT
Pub. L. 106–554, §1(a)(6) [title IV, §412(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–513, provided that: "Not later than 2 years after the date on which the demonstration project under section 1866A of the Social Security Act (this section), as added by subsection (a), is implemented, the Comptroller General of the United States shall submit to Congress a report on such demonstration project. The report shall include such recommendations with respect to changes to the demonstration project that the Comptroller General determines appropriate."

§1395cc–2. Provisions for administration of demonstration program

(a) General administrative authority

(1) Beneficiary eligibility

Except as otherwise provided by the Secretary, an individual shall only be eligible to receive benefits under the program under section 1395cc–1 of this title (in this section referred to as the "demonstration program") if such individual—

(A) is enrolled under the program under part B of this subchapter and entitled to benefits under part A of this subchapter; and

(B) is not enrolled in a Medicare+Choice plan under part C of this subchapter, an eli-
gible organization under a contract under section 1395mm of this title (or a similar organization operating under a demonstration project authority), an organization with an agreement under section 1395(a)(1)(A) of this title, or a PACE program under section 1395eee of this title.

(2) Secretary’s discretion as to scope of program

The Secretary may limit the implementation of the demonstration program to—

(A) a geographic area (or areas) that the Secretary designates for purposes of the program, based upon such criteria as the Secretary finds appropriate;

(B) a subgroup (or subgroups) of beneficiaries or individuals and entities furnishing items or services (otherwise eligible to participate in the program), selected on the basis of the number of such participants that the Secretary finds consistent with the effective and efficient implementation of the program;

(C) an element (or elements) of the program that the Secretary determines to be suitable for implementation; or

(D) any combination of any of the limits described in subparagraphs (A) through (C).

(3) Voluntary receipt of items and services

Items and services shall be furnished to an individual under the demonstration program only at the individual’s election.

(4) Agreements

The Secretary is authorized to enter into agreements with individuals and entities to furnish health care items and services to beneficiaries under the demonstration program.

(5) Program standards and criteria

The Secretary shall establish performance standards for the demonstration program including, as applicable, standards for quality of health care items and services, cost-effectiveness, beneficiary satisfaction, and such other factors as the Secretary finds appropriate. The eligibility of individuals or entities for the initial award, continuation, and renewal of agreements to provide health care items and services under the program shall be conditioned, at a minimum, on performance that meets or exceeds such standards.

(6) Administrative review of decisions affecting individuals and entities furnishing services

An individual or entity furnishing services under the demonstration program shall be entitled to a review by the program administrator (or, if the Secretary has not contracted with a program administrator, by the Secretary) of a decision not to enter into, or to terminate, or not to renew, an agreement with the entity to provide health care items or services under the program.

(7) Secretary’s review of marketing materials

An agreement with an individual or entity furnishing services under the demonstration program shall require the individual or entity to guarantee that it will not distribute materials that market items or services under the program without the Secretary’s prior review and approval.

(8) Payment in full

(A) In general

Except as provided in subparagraph (B), an individual or entity receiving payment from the Secretary under a contract or agreement under the demonstration program shall agree to accept such payment as payment in full, and such payment shall be in lieu of any payments to which the individual or entity would otherwise be entitled under this subchapter.

(B) Collection of deductibles and coinsurance

Such individual or entity may collect any applicable deductible or coinsurance amount from a beneficiary.

(b) Contracts for program administration

(1) In general

The Secretary may administer the demonstration program through a contract with a program administrator in accordance with the provisions of this subsection.

(2) Scope of program administrator contracts

The Secretary may enter into such contracts for a limited geographic area, or on a regional or national basis.

(3) Eligible contractors

The Secretary may contract for the administration of the program with—

(A) an entity that, under a contract under section 1395h or 1395a of this title, determines the amount of and makes payments for health care items and services furnished under this subchapter; or

(B) any other entity with substantial experience in managing the type of program concerned.

(4) Contract award, duration, and renewal

(A) In general

A contract under this subsection shall be for an initial term of up to three years, renewable for additional terms of up to three years.

(B) Noncompetitive award and renewal for entities administering part A or part B payments

The Secretary may enter or renew a contract under this subsection with an entity described in paragraph (3)(A) without regard to the requirements of section 6101 of title 41.

(5) Applicability of Federal Acquisition Regulation

The Federal Acquisition Regulation shall apply to program administration contracts under this subsection.

(6) Performance standards

The Secretary shall establish performance standards for the program administrator including, as applicable, standards for the quality and cost-effectiveness of the program administered, and such other factors as the Secretary finds appropriate. The eligibility of en-
entities for the initial award, continuation, and renewal of program administration contracts shall be conditioned, at a minimum, on performance that meets or exceeds such standards.

(7) Functions of program administrator

A program administrator shall perform any or all of the following functions, as specified by the Secretary:

(A) Agreements with entities furnishing health care items and services

Determine the qualifications of entities seeking to enter or renew agreements to provide services under the demonstration program, and as appropriate enter or renew (or refuse to enter or renew) such agreements on behalf of the Secretary.

(B) Establishment of payment rates

Negotiate or otherwise establish, subject to the Secretary’s approval, payment rates for covered health care items and services.

(C) Payment of claims or fees

Administer payments for health care items or services furnished under the program.

(D) Payment of bonuses

Using such guidelines as the Secretary shall establish, and subject to the approval of the Secretary, make bonus payments as described in subsection (c)(2)(B) of this section to entities furnishing items or services for which payment may be made under the program.

(E) Oversight

Monitor the compliance of individuals and entities with agreements under the program with the conditions of participation.

(F) Administrative review

Conduct reviews of adverse determinations specified in subsection (a)(6) of this section.

(G) Review of marketing materials

Conduct a review of marketing materials proposed by an entity furnishing services under the program.

(H) Additional functions

Perform such other functions as the Secretary may specify.

(8) Limitation of liability

The provisions of section 1320c-6(b) of this title shall apply with respect to activities of contractors and their officers, employees, and agents under a contract under this subsection.

(9) Information sharing

Notwithstanding section 1306 of this title and section 552a of title 5, the Secretary is authorized to disclose to an entity with a program administration contract under this subsection such information (including medical information) on individuals receiving health care items and services under the program as the entity may require to carry out its responsibilities under the contract.

(c) Rules applicable to both program agreements and program administration contracts

(1) Records, reports, and audits

The Secretary is authorized to require entities with agreements to provide health care items or services under the demonstration program, and entities with program administration contracts under subsection (b) of this section, to maintain adequate records, to afford the Secretary access to such records (including for audit purposes), and to furnish such reports and other materials (including audited financial statements and performance data) as the Secretary may require for purposes of implementation, oversight, and evaluation of the program and of individuals’ and entities’ effectiveness in performance of such agreements or contracts.

(2) Bonuses

Notwithstanding any other provision of law, but subject to subparagraph (B)(ii), the Secretary may make bonus payments under the demonstration program from the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in amounts that do not exceed the amounts authorized under the program in accordance with the following:

(A) Payments to program administrators

The Secretary may make bonus payments under the program to program administrators.

(B) Payments to entities furnishing services

(i) In general

Subject to clause (ii), the Secretary may make bonus payments to individuals or entities furnishing items or services for which payment may be made under the demonstration program, or may authorize the program administrator to make such bonus payments in accordance with such guidelines as the Secretary shall establish and subject to the Secretary’s approval.

(ii) Limitations

The Secretary may condition such payments on the achievement of such standards related to efficiency, improvement in processes or outcomes of care, or such other factors as the Secretary determines to be appropriate.

(3) Antidiscrimination limitation

The Secretary shall not enter into an agreement with an entity to provide health care items or services under the demonstration program, or with an entity to administer the program, unless such entity guarantees that it will not deny, limit, or condition the coverage or provision of benefits under the program, for individuals eligible to be enrolled under such program, based on any health status-related factor described in section 2702(a)(1)\(^1\) of the Public Health Service Act.

(d) Limitations on judicial review

The following actions and determinations with respect to the demonstration program shall not

\(^1\) See References in Text note below.
be subject to review by a judicial or administrative tribunal:

(1) Limiting the implementation of the program under subsection (a)(2) of this section.

(2) Establishment of program participation standards under subsection (a)(6) of this section or the denial or termination of, or refusal to renew, an agreement with an entity to provide health care items and services under the program.

(3) Establishment of program administration contract performance standards under subsection (b)(6) of this section, the refusal to renew a program administration contract, or the noncompetitive award or renewal of a program administration contract under subsection (b)(4)(B) of this section.

(4) Establishment of payment rates, through negotiation or otherwise, under a program agreement or a program administration contract.

(5) A determination with respect to the program (where specifically authorized by the program authority or by subsection (c)(2) of this section)—

(A) as to whether cost savings have been achieved, and the amount of savings; or

(B) as to whether, to whom, and in what amounts bonuses will be paid.

(c) Application limited to parts A and B

None of the provisions of this section or of the demonstration program shall apply to the programs under part C of this subchapter.

(f) Reports to Congress

Not later than two years after December 21, 2000, and biennially thereafter for six years, the Secretary shall report to Congress on the use of authorities under the demonstration program. Each report shall address the impact of the use of those authorities on expenditures, access, and quality under the programs under this subchapter.


References in Text

Parts A, B, and C of this subchapter, referred to in subsecs. (a)(1) and (e), are classified to sections 1395c et seq., 1395 et seq., and 1395w–21 et seq., respectively, of this title.


Codification

(3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of services, and outcomes measurement and research;
(4) encourage shared decision making between providers and patients;
(5) the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources;
(6) the appropriate use of culturally and ethnically sensitive health care delivery; and
(7) the financial effects on the health care marketplace of altering the incentives for care delivery and changing the allocation of resources.

(c) Administration by contract

(1) In general
Except as otherwise provided in this section, the Secretary may administer the demonstration program established under this section in a manner that is similar to the manner in which the demonstration program established under section 1395cc–1 of this title is administered in accordance with section 1395cc–2 of this title.

(2) Alternative payment systems
A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include proposals for the use of alternative payment systems for items and services provided to beneficiaries by the group that are designed to—
(A) encourage the delivery of high quality care while accomplishing the objectives described in subsection (b) of this section; and
(B) streamline documentation and reporting requirements otherwise required under this subchapter.

(3) Benefits
A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the original medicare fee-for-service program under parts A and B of this subchapter or the package of benefits available through a Medicare Advantage plan under part C of this subchapter. The criteria employed under the demonstration program under this section to evaluate outcomes and determine best practice guidelines and incentives shall not be used as a basis for the denial of medicare benefits under the demonstration program to patients against their wishes (or if the patient is incompetent, against the wishes of the patient’s surrogate) on the basis of the patient’s age or expected length of life or of the patient’s present or predicted disability, degree of medical dependency, or quality of life.

(d) Eligibility criteria
To be eligible to receive assistance under this section, an entity shall—
(1) be a health care group;
(2) meet quality standards established by the Secretary, including—
(A) the implementation of continuous quality improvement mechanisms that are aimed at integrating community-based support services, primary care, and referral care;
(B) the implementation of activities to increase the delivery of effective care to beneficiaries;
(C) encouraging patient participation in preference-based decisions;
(D) the implementation of activities to encourage the coordination and integration of medical service delivery; and
(E) the implementation of activities to measure and document the financial impact on the health care marketplace of altering the incentives of health care delivery and changing the allocation of resources; and
(3) meet such other requirements as the Secretary may establish.

(e) Waiver authority
The Secretary may waive such requirements of this subchapter and subchapter XI of this chapter as may be necessary to carry out the purposes of the demonstration program established under this section.

(f) Budget neutrality
With respect to the period of the demonstration program under subsection (b) of this section, the aggregate expenditures under this subchapter for such period shall not exceed the aggregate expenditures that would have been expended under this subchapter if the program established under this section had not been implemented.

(g) Notice requirements
In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this subchapter as a result of the participation of the individual in such program.

(h) Participation and support by Federal agencies
In carrying out the demonstration program under this section, the Secretary may direct—
(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;
(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and
(3) the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant medicare data to registry information from participating health care groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstra-
§ 1395cc–4. National pilot program on payment bundling

(a) Implementation

(1) In general

The Secretary shall establish a pilot program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services under this subchapter.

(2) Definitions

In this section:

(A) Applicable beneficiary

The term “applicable beneficiary” means an individual who—

(i) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B of such subchapter, but not enrolled under part C or a PACE program under section 1395eee of this title; and

(ii) is admitted to a hospital for an applicable condition.

(B) Applicable condition

The term “applicable condition” means 1 or more of 10 conditions selected by the Secretary. In selecting conditions under the preceding sentence, the Secretary shall take into consideration the following factors:

(i) Whether the conditions selected include a mix of chronic and acute conditions;

(ii) Whether the conditions selected include a mix of surgical and medical conditions;

(iii) Whether a condition is one for which there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished while reducing total expenditures under this subchapter.

(iv) Whether a condition has significant variation in—

(I) the number of readmissions; and

(II) the amount of expenditures for post-acute care spending under this subchapter.

(v) Whether a condition is high-volume and has high post-acute care expenditures under this subchapter.

(vi) Which conditions the Secretary determines are most amenable to bundling across the spectrum of care given practice patterns under this subchapter.

(C) Applicable services

The term “applicable services” means the following:

(i) Acute care inpatient services.

(ii) Physicians’ services delivered in and outside of an acute care hospital setting.

(iii) Outpatient hospital services, including emergency department services.

(iv) Post-acute care services, including home health services, skilled nursing services, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital.

(v) Other services the Secretary determines appropriate.

(D) Episode of care

(i) In general

Subject to clause (ii), the term “episode of care” means, with respect to an applicable condition and an applicable beneficiary, the period that includes—

(I) the 3 days prior to the admission of the applicable beneficiary to a hospital for the applicable condition;

(II) the length of stay of the applicable beneficiary in such hospital; and

(III) the 30 days following the discharge of the applicable beneficiary from such hospital.

(ii) Establishment of period by the Secretary

The Secretary, as appropriate, may establish a period (other than the period described in clause (i)) for an episode of care under the pilot program.

(E) Physicians’ services

The term “physicians’ services” has the meaning given such term in section 1395x(q) of this title.

(F) Pilot program

The term “pilot program” means the pilot program under this section.

(G) Provider of services

The term “provider of services” has the meaning given such term in section 1395x(u) of this title.

(H) Readmission

The term “readmission” has the meaning given such term in section 1395ww(q)(5)(E) of this title.

(I) Supplier

The term “supplier” has the meaning given such term in section 1395x(d) of this title.
(3) Deadline for implementation
The Secretary shall establish the pilot program not later than January 1, 2013.

(b) Developmental phase

(1) Determination of patient assessment instrument
The Secretary shall determine which patient assessment instrument (such as the Continuity Assessment Record and Evaluation (CARE) tool) shall be used under the pilot program to evaluate the applicable condition of an applicable beneficiary for purposes of determining the most clinically appropriate site for the provision of post-acute care to the applicable beneficiary.

(2) Development of quality measures for an episode of care and for post-acute care
(A) In general
The Secretary, in consultation with the Agency for Healthcare Research and Quality and the entity with a contract under section 1395aaa(a) of this title, shall develop quality measures for use in the pilot program—
(i) for episodes of care; and
(ii) for post-acute care.

(B) Site-neutral post-acute care quality measures
Any quality measures developed under subparagraph (A)(ii) shall be site-neutral.

(C) Coordination with quality measure development and endorsement procedures
The Secretary shall ensure that the development of quality measures under subparagraph (A) is done in a manner that is consistent with the measures developed and endorsed under section 1395aaa and 1395aaa–1 of this title that are applicable to all post-acute care settings.

(e) Details

(1) Duration
(A) In general
Subject to subparagraph (B), the pilot program shall be conducted for a period of 5 years.

(B) Expansion
The Secretary may, at any point after January 1, 2016, expand the duration and scope of the pilot program, to the extent determined appropriate by the Secretary, if—
(i) the Secretary determines that such expansion is expected to—
(I) reduce spending under this subchapter without reducing the quality of care; or
(II) improve the quality of care and reduce spending;
(ii) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under this subchapter; and
(iii) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under this subchapter for individuals.

(2) Participating providers of services and suppliers
(A) In general
An entity comprised of providers of services and suppliers, including a hospital, a physician group, a skilled nursing facility, and a home health agency, who are otherwise participating under this subchapter, may submit an application to the Secretary to provide applicable services to applicable individuals under this section.

(B) Requirements
The Secretary shall develop requirements for entities to participate in the pilot program under this section. Such requirements shall ensure that applicable beneficiaries have an adequate choice of providers of services and suppliers under the pilot program.

(3) Payment methodology
(A) In general
(i) Establishment of payment methods
The Secretary shall develop payment methods for the pilot program for entities participating in the pilot program. Such payment methods may include bundled payments and bids from entities for episodes of care. The Secretary shall make payments to the entity for services covered under this section.

(ii) No additional program expenditures
Payments under this section for applicable items and services under this subchapter (including payment for services described in subparagraph (B)) for applicable beneficiaries for a year shall be established in a manner that does not result in spending more for such entity for such beneficiaries than would otherwise be expended for such entity for such beneficiaries for such year if the pilot program were not implemented, as estimated by the Secretary.

(B) Inclusion of certain services
A payment methodology tested under the pilot program shall include payment for the furnishing of applicable services and other appropriate services, such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient-centered activities as determined appropriate by the Secretary.

(C) Bundled payments
(i) In general
A bundled payment under the pilot program shall—
(I) be comprehensive, covering the costs of applicable services and other appropriate services furnished to an individual during an episode of care (as determined by the Secretary); and
(II) be made to the entity which is participating in the pilot program.

(ii) Requirement for provision of applicable services and other appropriate services
Applicable services and other appropriate services for which payment is made

1So in original. Probably should be “sections”.
§ 1395cc–4

(1) In general

The Secretary shall establish quality measures (including quality measures of process, outcome, and structure) related to care provided by entities participating in the pilot program. Quality measures established under the preceding sentence shall include measures of the following:

(A) Functional status improvement.

(B) Reducing rates of avoidable hospital readmissions.

(C) Rates of discharge to the community.

(D) Rates of admission to an emergency room after a hospitalization.

(E) Incidence of health care acquired infections.

(F) Efficiency measures.

(G) Measures of patient-centeredness of care.

(H) Measures of patient perception of care.

(I) Other measures, including measures of patient outcomes, determined appropriate by the Secretary.

(B) Reporting on quality measures

(i) In general

A entity shall submit data to the Secretary on quality measures established under subparagraph (A) during each year of the pilot program (in a form and manner, subject to clause (iii), specified by the Secretary).

(ii) Submission of data through electronic health record

To the extent practicable, the Secretary shall specify that data on measures be submitted under clause (i) through the use of an qualified electronic health record (as defined in section 300jj(13) of this title) in a manner specified by the Secretary.

(d) Waiver

The Secretary may waive such provisions of this subchapter and subchapter XI as may be necessary to carry out the pilot program.

(e) Independent evaluation and reports on pilot program

(1) Independent evaluation

The Secretary shall conduct an independent evaluation of the pilot program, including the extent to which the pilot program has—

(A) Improved quality measures established under subsection (c)(4)(A);

(B) Improved health outcomes;

(C) Improved applicable beneficiary access to care; and

(D) Reduced spending under this subchapter.

(2) Reports

(A) Interim report

Not later than 2 years after the implementation of the pilot program, the Secretary shall submit to Congress a report on the initial results of the independent evaluation conducted under paragraph (1).

(B) Final report

Not later than 3 years after the implementation of the pilot program, the Secretary shall submit to Congress a report on the final results of the independent evaluation conducted under paragraph (1).

(f) Consultation

The Secretary shall consult with representatives of small rural hospitals, including critical access hospitals (as defined in section 1395x(mm)(1) of this title), regarding their participation in the pilot program. Such consultation shall include consideration of innovative methods of implementing bundled payments in hospitals described in the preceding sentence, taking into consideration any difficulties in doing so as a result of the low volume of services provided by such hospitals.

(g) Application of pilot program to continuing care hospitals

(1) In general

In conducting the pilot program, the Secretary shall apply the provisions of the program so as to separately pilot test the continuing care hospital model.

(2) Special rules

In pilot testing the continuing care hospital model under paragraph (1), the following rules shall apply:

(A) Such model shall be tested without the limitation to the conditions selected under subsection (a)(2)(B).

(B) Notwithstanding subsection (a)(2)(D), an episode of care shall be defined as the full period that a patient stays in the continuing care hospital plus the first 30 days following discharge from such hospital.

(3) Continuing care hospital defined

In this subsection, the term “continuing care hospital” means an entity that has demonstrated the ability to meet patient care and patient safety standards and that provides under common management the medical and rehabilitation services provided in inpatient rehabilitation hospitals and units (as defined in section 1395ww(d)(1)(B)(ii) of this title), long term care hospitals (as defined in section 1395ww(d)(1)(B)(iv)(I) of this title), and skilled nursing facilities (as defined in section 1395i–3(a) of this title) that are located in a hospital described in section 1395ww(d) of this title.

(h) Administration

Chapter 35 of title 44 shall not apply to the selection, testing, and evaluation of models or the expansion of such models under this section.

REFERENCES IN TEXT

Parts A, B, and C, referred to in subsec. (a)(2)(A)(i), are classified to sections 1395c et seq., 1395j et seq., and 1395w–21 et seq., respectively, of this title.

CODIFICATION

Another section 1866D of act Aug. 14, 1935, was renumbered section 1866E and is classified to section 1395cc–5 of this title.

AMENDMENTS


Subsec. (a)(2)(B), Pub. L. 111–148, §10308(a)(1), substituted “10 conditions” for “8 conditions”.

Subsec. (c)(1)(B), Pub. L. 111–148, §10308(a)(3), added subsec. (g) and struck out former subsec. (g). Prior to amendment, text read as follows: “The Secretary shall conduct a demonstration program (in this section referred to as the ‘demonstration program’) to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to provide home-based primary care services to high-cost chronically ill beneficiaries, make in-home visits, and are available 24 hours per day, 7 days per week to carry out plans of care that are tailored to the individual beneficiary’s chronic conditions and designed to achieve the results in subsection (a);

(ii) is organized at least in part for the purpose of providing physicians’ services;

(iii) has documented experience in providing home-based primary care services to high-cost chronically ill beneficiaries, as determined appropriate by the Secretary;

(iv) furnishes services to at least 200 applicable beneficiaries (as defined in subsection (d)) during each year of the demonstration program;

(v) has entered into an agreement with the Secretary;

(vi) uses electronic health information systems, remote monitoring, and mobile diagnostic technology; and

(vii) meets such other criteria as the Secretary determines to be appropriate to participate in the demonstration program.

The entity shall report on quality measures (in such form, manner, and frequency as specified by the Secretary, which may be for the group, for providers of services and suppliers, or both) and report to the Secretary (in a form, manner, and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the demonstration program.

(B) Physician

The term “physician” includes, except as the Secretary may otherwise provide, any individual who furnishes services for which payment may be made as physicians’ services and has the medical training or experience to fulfill the physician’s role described in subparagraph (A)(i).

(2) Participation of nurse practitioners and physician assistants

Nothing in this section shall be construed to prevent a nurse practitioner or physician assistant from participating in, or leading, a home-based primary care team as part of an independence at home medical practice if—

(A) all the requirements of this section are met; and

(G) achieving beneficiary and family caregiver satisfaction.

(1) Independence at home medical practice defined

In this section:

(A) In general

The term “independence at home medical practice” means a legal entity that—

(i) is comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners that provides care as part of a team that includes physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who have experience providing home-based primary care to applicable beneficiaries, make in-home visits, and are available 24 hours per day, 7 days per week to carry out plans of care that are tailored to the individual beneficiary’s chronic conditions and designed to achieve the results in subsection (a);

(ii) is organized at least in part for the purpose of providing physicians’ services;

(iii) has documented experience in providing home-based primary care services to high-cost chronically ill beneficiaries, as determined appropriate by the Secretary;

(iv) furnishes services to at least 200 applicable beneficiaries (as defined in subsection (d)) during each year of the demonstration program;

(v) has entered into an agreement with the Secretary;

(vi) uses electronic health information systems, remote monitoring, and mobile diagnostic technology; and

(vii) meets such other criteria as the Secretary determines to be appropriate to participate in the demonstration program.

The entity shall report on quality measures (in such form, manner, and frequency as specified by the Secretary, which may be for the group, for providers of services and suppliers, or both) and report to the Secretary (in a form, manner, and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the demonstration program.

(B) Physician

The term “physician” includes, except as the Secretary may otherwise provide, any individual who furnishes services for which payment may be made as physicians’ services and has the medical training or experience to fulfill the physician’s role described in subparagraph (A)(i).
(B) the nurse practitioner or physician assistant, as the case may be, is acting consistent with State law; and

(C) the nurse practitioner or physician assistant has the medical training or experience to fulfill the nurse practitioner or physician assistant role described in paragraph (1)(A)(i).

(3) Inclusion of providers and practitioners

Nothing in this subsection shall be construed as preventing an independence at home medical practice from including a provider of services or a participating practitioner described in section 1395u(b)(18)(C) of this title that is affiliated with the practice under an arrangement structured so that such provider of services or practitioner participates in the demonstration program and shares in any savings under the demonstration program.

(4) Quality and performance standards

The Secretary shall develop quality performance standards for independence at home medical practices participating in the demonstration program.

(c) Payment methodology

(1) Establishment of target spending level

The Secretary shall establish an estimated annual spending target, for the amount the Secretary estimates would have been spent in the absence of the demonstration, for items and services covered under parts A and B furnished to applicable beneficiaries for each qualifying independence at home medical practice under this section. Such spending targets shall be determined on a per capita basis. Such spending targets shall include a risk corridor that takes into account normal variation in expenditures for items and services covered under parts A and B furnished to such beneficiaries with the size of the corridor being related to the number of applicable beneficiaries furnished services by each independence at home medical practice. The spending targets may also be adjusted for other factors as the Secretary determines appropriate.

(2) Incentive payments

Subject to performance on quality measures, a qualifying independence at home medical practice is eligible to receive an incentive payment under this section if actual expenditures for a year for the applicable beneficiaries it enrolls are less than the estimated spending target established under paragraph (1) for such year. An incentive payment for such year shall be equal to a portion (as determined by the Secretary) of the amount by which actual expenditures (including incentive payments under this paragraph) for applicable beneficiaries under parts A and B for such year are estimated to be less than 5 percent less than the estimated spending target for such year, as determined under paragraph (1).

(d) Applicable beneficiaries

(1) Definition

In this section, the term “applicable beneficiary” means, with respect to a qualifying independence at home medical practice, an individual who the practice has determined—

(A) is entitled to benefits under part A and enrolled for benefits under part B;

(B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1395eee of this title;

(C) has 2 or more chronic illnesses, such as congestive heart failure, diabetes, other dementias designated by the Secretary, chronic obstructive pulmonary disease, ischemic heart disease, stroke, Alzheimer’s Disease and neurodegenerative diseases, and other diseases and conditions designated by the Secretary which result in high costs under this subchapter;

(D) within the past 12 months has had a nonelective hospital admission;

(E) within the past 12 months has received acute or subacute rehabilitation services;

(F) has 2 or more functional dependencies requiring the assistance of another person (such as bathing, dressing, toileting, walking, or feeding); and

(G) meets such other criteria as the Secretary determines appropriate.

(2) Patient election to participate

The Secretary shall determine an appropriate method of ensuring that applicable beneficiaries have agreed to enroll in an independence at home medical practice under the demonstration program. Enrollment in the demonstration program shall be voluntary.

(3) Beneficiary access to services

Nothing in this section shall be construed as encouraging physicians or nurse practitioners to limit applicable beneficiary access to services covered under this subchapter and applicable beneficiaries shall not be required to relinquish access to any benefit under this subchapter as a condition of receiving services from an independence at home medical practice.

(e) Implementation

(1) Starting date

The demonstration program shall begin no later than January 1, 2012. An agreement with an independence at home medical practice under the demonstration program may cover not more than a 3-year period.

(2) No physician duplication in demonstration participation

The Secretary shall not pay an independence at home medical practice under this section that participates in section 1395jjj of this title.

(3) No beneficiary duplication in demonstration participation

The Secretary shall ensure that no applicable beneficiary enrolled in an independence at home medical practice under this section is participating in the programs under section 1395jjj of this title.

(4) Preference

In approving an independence at home medical practice, the Secretary shall give preference to practices that are—

(A) located in high-cost areas of the country;
(B) have experience in furnishing health care services to applicable beneficiaries in the home; and
(C) use electronic medical records, health information technology, and individualized plans of care.

(5) Limitation on number of practices
In selecting qualified independence at home medical practices to participate under the demonstration program, the Secretary shall limit the number of such practices so that the number of applicable beneficiaries that may participate in the demonstration program does not exceed 10,000.

(6) Waiver
The Secretary may waive such provisions of this subchapter and subchapter XI as the Secretary determines necessary in order to implement the demonstration program.

(7) Administration
Chapter 35 of title 44 shall not apply to this section.

(f) Evaluation and monitoring

(1) In general
The Secretary shall evaluate each independence at home medical practice under the demonstration program to assess whether the practice achieved the results described in subsection (a).

(2) Monitoring applicable beneficiaries
The Secretary may monitor data on expenditures and quality of services under this subchapter after an applicable beneficiary discontinues receiving services under this subchapter through a qualifying independence at home medical practice.

(g) Reports to Congress
The Secretary shall conduct an independent evaluation of the demonstration program and submit to Congress a final report, including best practices under the demonstration program. Such report shall include an analysis of the demonstration program on coordination of care, beneficiary access to services, and the quality of health care services provided to applicable beneficiaries.

(h) Funding
For purposes of administering and carrying out the demonstration program, other than for payments for items and services furnished under this subchapter and incentive payments under subsection (c), in addition to funds otherwise appropriated, there shall be transferred to the Secretary for the Center for Medicare & Medicaid Services Program Management Account from the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395l of this title (in proportions determined appropriate by the Secretary) $5,000,000 for each of fiscal years 2010 through 2015. Amounts transferred under this subsection for a fiscal year shall be available until expended.

(i) Termination

(1) Mandatory termination
The Secretary shall terminate an agreement with an independence at home medical practice if—
(A) the Secretary estimates or determines that such practice will not receive an incentive payment for the second of 2 consecutive years under the demonstration program; or
(B) such practice fails to meet quality standards during any year of the demonstration program.

(2) Permissive termination
The Secretary may terminate an agreement with an independence at home medical practice for such other reasons determined appropriate by the Secretary.

§ 1395dd. Examination and treatment for emergency medical conditions and women in labor

(a) Medical screening requirement
In the case of a hospital that has a hospital emergency department, if any individual (whether or not eligible for benefits under this subchapter) comes to the emergency department and a request is made on the individual’s behalf for examination or treatment for a medical condition, the hospital must provide for an appropriate medical screening examination within the capability of the hospital’s emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition (within the meaning of subsection (e)(1) of this section) exists.

(b) Necessary stabilizing treatment for emergency medical conditions and labor

(1) In general
If any individual (whether or not eligible for benefits under this subchapter) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—
(A) within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition, or
(B) for transfer of the individual to another medical facility in accordance with subsection (c) of this section.

(2) Refusal to consent to treatment
A hospital is deemed to meet the requirement of paragraph (1)(A) with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs...
the individual (or a person acting on the individual’s behalf) of the risks and benefits to the individual of such examination and treatment, but the individual (or a person acting on the individual’s behalf) refuses to consent to the examination and treatment. The hospital shall take all reasonable steps to secure the individual’s (or person’s) written informed consent to refuse such examination and treatment.

(3) Refusal to consent to transfer

A hospital is deemed to meet the requirement of paragraph (1) with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with subsection (c) of this section and informs the individual (or a person acting on the individual’s behalf) of the risks and benefits to the individual of such transfer, but the individual (or a person acting on the individual’s behalf) refuses to consent to the transfer. The hospital shall take all reasonable steps to secure the individual’s (or person’s) written informed consent to refuse such transfer.

(c) Restricting transfers until individual stabilized

(1) Rule

If an individual at a hospital has an emergency medical condition which has not been stabilized (within the meaning of subsection (e)(3)(B) of this section), the hospital may not transfer the individual unless—

(A)(i) the individual (or a legally responsible person acting on the individual’s behalf) after being informed of the hospital’s obligations under this section and of the risk of transfer, in writing requests transfer to another medical facility,

(ii) a physician (within the meaning of section 1395x(r)(1) of this title) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child from effecting the transfer, or

(iii) if a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as defined by the Secretary in regulations) has signed a certification described in clause (ii) after a physician (as defined in section 1395x(r)(1) of this title), in consultation with the person, has made the determination described in such clause, and subsequently countersigns the certification; and

(B) the transfer is an appropriate transfer (within the meaning of paragraph (2)) to that facility.

A certification described in clause (ii) or (iii) of subparagraph (A) shall include a summary of the risks and benefits upon which the certification is based.

(2) Appropriate transfer

An appropriate transfer to a medical facility is a transfer—

(A) in which the transferring hospital provides the medical treatment within its capacity which minimizes the risks to the individual’s health and, in the case of a woman in labor, the health of the unborn child;

(B) in which the receiving facility—

(i) has available space and qualified personnel for the treatment of the individual, and

(ii) has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(C) in which the transferring hospital sends to the receiving facility all medical records (or copies thereof), related to the emergency condition for which the individual has presented, available at the time of the transfer, including records related to the individual’s emergency medical condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) provided under paragraph (1)(A), and the name and address of any on-call physician, as required including the use of necessary and medically appropriate life support measures during the transfer; and

(E) which meets such other requirements as the Secretary may find necessary in the interest of the health and safety of individuals transferred.

(d) Enforcement

(1) Civil money penalties

(A) A participating hospital that negligently violates a requirement of this section is subject to a civil money penalty of not more than $50,000 (or not more than $25,000 in the case of a hospital with less than 100 beds) for each such violation. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply with respect to a penalty or proceeding under section 1320a–7a(a) of this title.

(B) Subject to subparagraph (C), any physician who is responsible for the examination, treatment, or transfer of an individual in a participating hospital, including a physician on-call for the care of such an individual, and who negligently violates a requirement of this section, including a physician who—

(i) signs a certification under subsection (c)(1)(A) of this section that the medical benefits reasonably to be expected from a transfer to another facility outweigh the risks associated with the transfer, if the physician knew or should have known that the benefits did not outweigh the risks, or

(ii) misrepresents an individual’s condition or other information, including a hospital’s obligations under this section,
is subject to a civil money penalty of not more than $50,000 for each such violation and, if the violation is gross and flagrant or is repeated, to exclusion from participation in this subchapter and State health care programs. The provisions of section 1320a–7a of this title (other than the first and second sentences of subsection (a) and subsection (b)) shall apply to a civil money penalty and exclusion under this subparagraph in the same manner as such provisions apply with respect to a penalty, exclusion, or proceeding under section 1320a–7a(a) of this title.

(C) If, after an initial examination, a physician determines that the individual requires the services of a physician listed by the hospital on its list of on-call physicians (required to be maintained under section 1395cc(a)(1)(I) of this title) and notifies the on-call physician and the on-call physician fails or refuses to appear within a reasonable period of time, and the physician orders the transfer of the individual because the physician determines that without the services of the on-call physician the benefits of transfer outweigh the risks of transfer, the physician authorizing the transfer shall not be subject to a penalty under subparagraph (B). However, the previous sentence shall not apply to the hospital or to the on-call physician who failed or refused to appear.

(2) Civil enforcement

(A) Personal harm

Any individual who suffers personal harm as a direct result of a participating hospital’s violation of a requirement of this section may, in a civil action against the participating hospital, obtain those damages available for personal injury under the law of the State in which the hospital is located, and such equitable relief as is appropriate.

(B) Financial loss to other medical facility

Any medical facility that suffers a financial loss as a direct result of a participating hospital’s violation of a requirement of this section may, in a civil action against the participating hospital, obtain those damages available for financial loss, under the law of the State in which the hospital is located, and such equitable relief as is appropriate.

(C) Limitations on actions

No action may be brought under this paragraph more than two years after the date of the violation with respect to which the action is brought.

(3) Consultation with peer review organizations

In considering allegations of violations of the requirements of this section in imposing sanctions under paragraph (1) or in terminating a hospital’s participation under this subchapter, the Secretary shall request the appropriate utilization and quality control peer review organization (with a contract under part B of subchapter XI of this chapter) to assess whether the individual involved had an emergency medical condition which had not been stabilized, and provide a report on its findings. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall request such a review before effecting a sanction under paragraph (1) and shall provide a period of at least 60 days for such review. Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital’s participation under this subchapter for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization’s report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.

(4) Notice upon closing an investigation

The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this section is closed.

(e) Definitions

In this section:

(1) The term ‘emergency medical condition’ means—

(A) 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 health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(ii) serious impairment to bodily functions, or

(iii) serious dysfunction of any bodily organ or part;

(B) with respect to a pregnant woman who is having contractions—

(i) that there is inadequate time to effect a safe transfer to another hospital before delivery, or

(ii) that transfer may pose a threat to the health or safety of the woman or the unborn child.

(2) The term “participating hospital” means a hospital that has entered into a provider agreement under section 1395cc of this title.

(3)(A) The term “to stabilize” means, with respect to an emergency medical condition described in paragraph (1)(A), to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or, with respect to an emergency medical condition described in paragraph (1)(B), to deliver (including the placenta).

(B) The term “stabilized” means, with respect to an emergency medical condition described in paragraph (1)(A), that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility, or, with respect to an emer-
emergency medical condition described in paragraph (1)(B), that the woman has delivered (including the placenta).

(4) The term ‘‘transfer’’ means the movement (including the discharge) of an individual outside a hospital’s facilities at the discretion of any person employed by (or affiliated with or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (A) has been declared dead, or (B) leaves the facility without the permission of any such person.

(5) The term ‘‘hospital’’ includes a critical access hospital (as defined in section 1395x(m)(1) of this title).

(f) Preemption

The provisions of this section do not preempt any State or local law requirement, except to the extent that the requirement directly conflicts with a requirement of this section.

(g) Nondiscrimination

A participating hospital that has specialized capabilities or facilities (such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as identified by the Secretary in regulation) shall not refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

(h) No delay in examination or treatment

A participating hospital may not delay provision of an appropriate medical screening examination required under subsection (a) of this section or further medical examination and treatment required under subsection (b) of this section in order to inquire about the individual’s method of payment or insurance status.

(i) Whistleblower protections

A participating hospital may not penalize or take adverse action against a qualified medical professional described in subsection (c)(1)(A)(ii) of this section or a physician because the person or physician refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized or against any hospital employee because the employee reports a violation of a requirement of this section.


References in Text

Part B of subchapter XI of this chapter, referred to in subsec. (d)(3), is classified to section 1320c et seq. of this title.

Prior Provisions


Amendments


Subsec. (d)(3). Pub. L. 108–173, §944(c)(1), inserted ‘‘or in terminating a hospital’s participation under this subchapter for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide for a period of 5 days for such review. The Secretary shall provide a copy of the organization’s report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.’’

1997—Subsec. (e)(5). Pub. L. 105–33 substituted ‘‘critical access’’ for ‘‘rural primary care’’.


Subsec. (d)(1). Pub. L. 101–508, §4008(b)(3)(A)(i), (ii), redesignated par. (2) as (1) and struck out former par. (1) which read as follows: ‘‘If a hospital knowingly and willfully, or negligently, fails to meet the requirement of this section, such hospital is subject to—

(‘‘A’’) termination of its provider agreement under this subchapter in accordance with section 1395cc(b) of this title, or

(‘‘B’’) at the option of the Secretary, suspension of such agreement for such period of time as the Secretary determines to be appropriate, upon reasonable notice to the hospital and to the public.’’


Subsec. (d)(1). Pub. L. 101–508, §4008(b)(3)(A)(i), (ii), redesignated par. (2) as (1) and struck out former par. (1) which read as follows: ‘‘If a hospital knowingly and willfully, or negligently, fails to meet the requirement of this section, such hospital is subject to—

(‘‘A’’) termination of its provider agreement under this subchapter in accordance with section 1395cc(b) of this title, or

(‘‘B’’) at the option of the Secretary, suspension of such agreement for such period of time as the Secretary determines to be appropriate, upon reasonable notice to the hospital and to the public.’’


“(or not more than $25,000 in the case of a hospital with less than 100 beds)” after “$50,000”.


Subsec. (c)(2)(B). Pub. L. 101–239, § 6211(c)(5)(A), (g)(1)(B), redesignated subpar. (A) as (B) and substituted “the individual” for “for the patient” in cls. (i) and (ii). Former subpar. (D) redesignated (C).

Subsec. (c)(2)(C). Pub. L. 101–239, § 6211(c)(5)(A), (d), redesignated subpar. (B) as (C) and substituted “sends to” for “provides” and “all medical records (or copies thereof)” for “the individual’s medical record (or copies thereof)” where the individual has presented, available at the time of the transfer, including records related to the individual’s emergency medical condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and the informed written consent or certification (or copies thereof) provided under paragraph (1)(A), and the name and address of any on-call physician (described in subsection (d)(2)(C) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment for “with appropriate medical records (or copies thereof) of the examination and treatment effectuated at the transferring hospital”. Former subpar. (C) redesignated (D).

Subsec. (c)(2)(D). Pub. L. 101–239, § 6211(c)(5)(A), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Subsec. (c)(2)(E). Pub. L. 101–239, § 6211(c)(5)(A), (g)(1)(B), redesignated subpar. (D) as (E) and substituted “individuals” for “patients”.

Subsec. (d)(2)(B). Pub. L. 101–239, § 6211(e)(1), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “The responsible physician in a participating hospital with respect to the hospital’s violation of a requirement of a requirement of this subsection is subject to the sanctions described in section 1395dd(a)(2) of this title, except that, for purposes of this subparagraph, the civil money penalty with respect to each violation may not exceed $50,000, rather than $2,000.”

Subsec. (d)(2)(C). Pub. L. 101–239, § 6211(e)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: “As used in this paragraph, the term ‘responsible physician’ means, with respect to a hospital’s violation of a requirement of this section, a physician who—

“(i) is employed by, or under contract with, the participating hospital, and

“(ii) acting as such an employee or under such a contract, has professional responsibility for the provision of examinations or treatments for the individual, or transfers of the individual, with respect to which the violation occurred.”

Subsec. (e)(1). Pub. L. 101–239, § 6211(h)(1)(A), substituted “means” and “means 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—

“(A) placing the patient’s health in serious jeopardy,

“(B) serious impairment to bodily functions, or

“(C) serious dysfunction of any bodily organ or part.”

Subsec. (e)(2). Pub. L. 101–239, § 6211(h)(1)(B), (E), redesignated par. (3) as (2) and struck out former par. (2) which defined “active labor”.


Subsec. (e)(5)(A). Pub. L. 101–239, § 6211(h)(1)(C), substituted “emergency medical condition described in paragraph (1)(A)” for “emergency medical condition”, “likely to result from or occur during” for “for” and “from a facility” for “from a facility”.

Subsec. (e)(6)(A). Pub. L. 101–239, § 6211(h)(1)(C), redesignated subpar. (A) as (B) and substituted “the individual” for “the patient” and “the individual’s medical condition” for “the patient’s medical condition”.

Subsec. (e)(6)(B). Pub. L. 101–239, § 6211(h)(1)(C), redesignated subpar. (B) as (C) and substituted “sends to” for “provides” and “all medical records (or copies thereof)” for “the individual’s medical record (or copies thereof)” where the individual has presented, available at the time of the transfer, including records related to the individual’s emergency medical condition, observations of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and the informed written consent or certification (or copies thereof) provided under paragraph (1)(A), and the name and address of any on-call physician (described in subsection (d)(2)(C) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment for “with appropriate medical records (or copies thereof) of the examination and treatment effectuated at the transferring hospital”. Former subpar. (C) redesignated (D).

Subsec. (f)(1)(A). Pub. L. 101–239, § 6211(h)(2)(A), redesignated subpar. (A) as (B) and inserted at end “A certification described in subsection (e)(4)(B) of this section) or is in active labor”, and “the individual” for “the patient” in cls. (i) and (ii). Former subpar. (D) redesignated (C).


Subsec. (a). Pub. L. 101–239, § 6211(h)(2)(B), directed the amendment of subsec. (a) by striking out “or” to determine if the individual is in active labor (within the meaning of subsection (e)(2) of this section)” after “exists.

Pub. L. 101–139, § 6211(a), substituted “hospital’s emergency department, including ancillary services routinely available to the emergency department,” for “hospital’s emergency department”, amended subsec. (i) generally. Prior to amendment, subsec. (i) read as follows: “A participating hospital may not penalize or take adverse action against a physician because the physician refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized.”

1989—Pub. L. 101–239, § 6211(h)(2)(B), struck out “or to provide for treatment of the labor” after “stabilize the medical condition”.

Subsec. (b)(2). Pub. L. 101–239, § 6211(b)(1), inserted “and informs the individual (or a person acting on the individual’s behalf) of the risks and benefits to the individual of such examination and treatment,” after “in that paragraph”, substituted “and treatment,” for “or treatment.”, and inserted at end “The hospital shall take all reasonable steps to secure the individual’s (or person’s) written informed consent to refuse such examination and treatment.”

Subsec. (b)(3). Pub. L. 101–239, § 6211(b)(2), inserted “and informs the individual (or a person acting on the individual’s behalf) of the risks and benefits to the individual of such transfer,” after “subsection (c) of this section” and inserted at end “The hospital shall take all reasonable steps to secure the individual’s (or person’s) written informed consent to refuse such transfer.”


Subsec. (c)(1). Pub. L. 101–239, § 6211(c)(4), (g)(1)(B), (h)(2)(E), in introductory provisions, substituted “an individual” for “a patient”, “subsection (e)(3)(B) of this section” for “subsection (e)(2)(B) of this section” or is in active labor”, and “the individual” for “the patient”, and inserted at end “A certification described in clause (ii) or (iii) of subparagraph (A) shall include a summary of the risks and benefits upon which the certification is based.”

Subsec. (c)(1)(A)(i). Pub. L. 101–239, § 6211(c)(1), (g)(1)(B), substituted “the individual” for “for the patient”, “the individual’s behalf” for “for the patient’s behalf”, and “after being informed of the hospital’s obligations under this section and of the risk of transfer, in writing requests transfer to another medical facility” for “requests that the transfer be effected”.

Subsec. (c)(1)(A)(ii). Pub. L. 101–239, § 6211(c)(2)(B), (3), (g)(1)(B), substituted “has signed a certification that based upon the information available at the time of transfer, as determined by the responsible physician when a physician is not readily available in the emergency department, has signed a certification that, based upon the reasonable risks and benefits to the patient and the information available at the time of transfer, as determined by the physician when a physician is not readily available in the emergency department, has signed a certification that, based upon the reasonable risks and benefits to the patient and the circumstances of the situation, the individual is in active labor”, and “and in the case of labor, to the unborn child” for “individual’s medical condition”.

"or occur during" after "to result", and "or, with respect to an emergency medical condition described in paragraph (1)(B), that the woman has delivered (including the placenta)" after "from a facility\".
Pub. L. 101–239, §6211(g)(2), substituted "an individual" for "a patient" in two places.
Subsecs. (g) to (i). Pub. L. 101–239, §6211(f), added subsecs. (g) to (i).
1987—Subsec. (d)(1). Pub. L. 100–203, §4009(a)(2), which directed insertion of a provision related to imposing the sanction described in section 1395g(a)(2)(A) of this title, was amended generally by Pub. L. 100–360, §411(b)(B)(A)(1), so that it does not amend par. (1).
Subsec. (d)(2). Pub. L. 100–203, §4009(a)(1), as amended by Pub. L. 100–360, §411(b)(B)(A)(1), as amended by Pub. L. 100–485, §608(d)(18)(E), substituted subpars. (A) and (B) for "in addition to the other grounds for imposition of a civil money penalty under section 1320a-7a(a) of this title, a participating hospital that knowingly violates a requirement of this section and the responsible physician in the hospital with respect to such a violation are each subject, under that section, to a civil money penalty of not more than $25,000 for each such violation", designated second sentence as subpar. (C), substituted "this paragraph" for "the previous sentence", and redesignated former subpars. (A) and (B) as clis. (i) and (ii), respectively, of subpar. (C).
1986—Subsec. (b)(2), (3). Pub. L. 99–514 struck out "legally responsible" after "individual or a\".
Subsec. (e)(3). Pub. L. 99–514 struck out "and has, under the agreement, obligated itself to comply with the requirements of this section" after "section 1385cc of this title\".

Effective Date of 2003 Amendment
Pub. L. 106–173, title IX, §944(c)(2), Dec. 8, 2003, 117 Stat. 2423, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to terminations of participation initiated on or after the date of the enactment of this Act [Dec. 8, 2003]."•

Effective Date of 1997 Amendment
Amendment by Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 2421(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Effective Date of 1996 Amendment
Amendment by section 4008(b)(1)–(3)(A) of Pub. L. 100–508 applicable to actions occurring on or after the first day of the sixth month beginning after Nov. 5, 1990, see section 4008(b)(4) of Pub. L. 101–508, set out as a note under section 1395ccc of this title.

Amendment by section 4008(b)(1) of Pub. L. 100–508 effective on the first day of the first month beginning more than 60 days after Nov. 5, 1990, see section 4008(b)(1)(C) of Pub. L. 101–508, as amended, set out as a note under section 1395c–3 of this title.

Section 4207(a)(4), formerly 4027(a)(4), of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §146(d)(4), (5)(B), Oct. 31, 1994, 108 Stat. 4444, provided that: "The amendments made by paragraphs (2) and (3) [amending this section] shall apply to actions occurring on or after the first day of the sixth month beginning after the date of the enactment of this Act [Nov. 5, 1990]."

Effective Date of 1989 Amendment
Section 6211(i) of Pub. L. 101–239 provided that: "The amendments made by this section [amending this section] shall take effect on the first day of the first month that begins more than 180 days after the date of the enactment of this Act (Dec. 19, 1989), without regard to whether regulations to carry out such amendments have been promulgated by such date."

Effective Date of 1988 Amendments
Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 6006(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a)(2) of Pub. L. 100–360, set out as a reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Effective Date of 1987 Amendment
Section 4009(a)(2), formerly §4009(a)(3), of Pub. L. 100–203, as redesignated by Pub. L. 100–360, §411(b)(8)(A)(i), July 1, 1988, 102 Stat. 772, provided that: "The amendments made by this subsection [amending this section] shall apply to actions occurring on or after the date of the enactment of this Act [Dec. 22, 1987]."

Effective Date of 1986 Amendment

Effective Date
Section 9121(c) of Pub. L. 99–272 provided that: "The amendments made by this section [enacting this section and amending section 1395cc of this title] shall take effect on the first day of the first month that begins at least 90 days after the date of the enactment of this Act [Apr. 7, 1986]."

Short Title
This section is popularly known as the Emergency Medical Treatment and Labor Act (EMTALA).

Emergency Medical Treatment and Labor Act (EMTALA) Technical Advisory Group

"(b) Membership.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—

"(1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;

"(2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or
cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;

“(3) 2 shall represent patients;

“(4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and

“(5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

“(c) General Responsibilities.—The Advisory Group—

“(1) shall review EMTALA regulations;

“(2) may provide advice and recommendations to the Secretary with respect to those regulations and the application to hospitals and physicians;

“(3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and

“(4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.

“(d) Administrative Matters.—

“(1) Chairperson.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.

“(2) Meetings.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.

“(e) Termination.—The Advisory Group shall terminate 30 months after the date of its first meeting.

“(f) Waiver of Administrative Limitation.—The Secretary shall establish the Advisory Group notwithstanding any limitation that may apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

FEDERAL REIMBURSEMENT OF EMERGENCY HEALTH SERVICES Furnished to Undocumented Aliens


“(a) Total Amount Available for Allotment.—

“(1) in General.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $250,000,000 for each of fiscal years 2005 through 2008 for the purpose of making allotments under this section.

“(2) Availability.—Funds appropriated under paragraph (1) shall remain available until expended.

“(b) State Allotments.—

“(1) Based on Percentage of Undocumented Aliens.—

“(A) in General.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $157,000,000 of such amount to make allotments for such fiscal year in accordance with subparagraph (B).

“(B) Formula.—The amount of the allotment for payments to eligible providers in each State for a fiscal year shall be equal to the product of—

“(i) the total amount available for allotments under this paragraph for the fiscal year; and

“(ii) the percentage of undocumented aliens residing in the State as compared to the total number of such aliens residing in all States, as determined by the Statistics Division of the Immigration and Naturalization Service, as of January 2003, based on the 2000 decennial census.

“(2) based on number of undocumented alien apprehensions states.—

“(A) in General.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $825,000,000 of such amount to make allotments, in addition to amounts allotted under paragraph (1), for each fiscal year for each of the 6 States with the highest number of undocumented alien apprehensions for such fiscal year.

“(B) Determination of Allotments.—The amount of the allotment for each State described in subparagraph (A) for a fiscal year shall be equal to the product of—

“(i) the total amount available for allotments under this paragraph for the fiscal year; and

“(ii) the percentage of undocumented alien apprehensions in the State in that fiscal year as compared to the total of such apprehensions for all such States for the preceding fiscal year.

“(C) Data.—For purposes of this paragraph, the highest number of undocumented alien apprehensions for a fiscal year shall be based on the apprehension rates for the 4-consecutive-quarter period ending before the beginning of the fiscal year for which information is available for undocumented aliens in such States, as reported by the Department of Homeland Security.

“(c) Use of Funds.—

“(1) Authority to Make Payments.—From the allotments made for a State under subsection (b) for a fiscal year, the Secretary shall pay the amount (subject to the total amount available from such allotments) determined under paragraph (2) directly to eligible providers located in the State for the provision of eligible services to aliens described in paragraph (5) to the extent that the eligible provider was not otherwise reimbursed (through insurance or otherwise) for such services during that fiscal year.

“(2) Determination of Payment Amounts.—

“(A) in General.—Subject to subparagraph (B), the payment amount determined under this paragraph shall be an amount determined by the Secretary that is equal to the lesser of—

“(i) the amount that the provider demonstrates was incurred for the provision of such services; or

“(ii) amounts determined under a methodology established by the Secretary for purposes of this subsection.

“(B) Pro-Rata Reduction.—If the amount of funds allotted to a State under subsection (b) for a fiscal year is insufficient to ensure that each eligible provider in that State receives the amount of payment calculated under subparagraph (A), the Secretary shall reduce the amount of payment with respect to each eligible provider to ensure that the entire amount allotted to the State for that fiscal year is paid to such eligible providers.

“(3) Methodology.—In establishing a methodology under paragraph (2)(A)(i), the Secretary—

“(A) may establish different methodologies for types of eligible providers;

“(B) may base payments for hospital services on estimated hospital charges, adjusted to estimated cost, through the application of hospital-specific cost-to-charge ratios;

“(C) shall provide for the election by a hospital to receive either payments to the hospital for—

“(i) hospital and physician services; or

“(ii) hospital services and for a portion of the on-call payments made by the hospital to physicians; and

“(D) shall make quarterly payments under this section to eligible providers.

If a hospital makes the election under subparagraph (C)(i), the hospital shall pass on payments for services of a physician to the physician and may not charge any administrative or other fee with respect to such payments.

“(4) Limitation on Use of Funds.—Payments made to eligible providers in a State from allotments made
under subsection (b) for a fiscal year may only be used for costs incurred in providing eligible services to aliens described in paragraph (5).

(3) Aliens described.—For purposes of paragraphs (1) and (2), aliens described in this paragraph are any of the following:

(A) Undocumented aliens.

(B) Aliens who have been paroled into the United States at a United States port of entry for the purpose of receiving eligible services.

(C) Mexican citizens permitted to enter the United States for not more than 72 hours under the authority of a biometric machine readable border crossing identification card (also referred to as a ‘laser visa’) issued in accordance with the requirements of regulations prescribed under section 101(a)(6) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(6)).

(D) APPLICABLE DEFINITIONS.—

(1) DEADLINE FOR ESTABLISHMENT OF APPLICATION PROCESS.—

(A) IN GENERAL.—Not later than September 1, 2004, the Secretary shall establish a process under which eligible providers located in a State may request payments under subsection (c).

(B) INCLUSION OF MEASURES TO COMBAT FRAUD AND ABUSE.—The Secretary shall include in the process established under subparagraph (A) measures to ensure that inappropriate, excessive, or fraudulent payments are not made from the allotments determined under subsection (b), including certification by the eligible provider of the veracity of the payment request.

(3) HOSPITAL.—The term ‘hospital’ has the meaning given such term in section 1861(e) of the Social Security Act (42 U.S.C. 1395dd), and related hospital inpatient and outpatient services and ambulance services (as defined by the Secretary).

(3) HOSPITAL.—The term ‘hospital’ has the meaning given such term in section 1861(e) of the Social Security Act (42 U.S.C. 1395dd), and related hospital inpatient and outpatient services and ambulance services (as defined by the Secretary).

(4) PHYSICIAN.—The term ‘physician’ has the meaning given that term in section 1861(r) of the Social Security Act (42 U.S.C. 1395x(r)).

(5) INDIAN TRIBE; TRIBAL ORGANIZATION.—The terms ‘Indian tribe’ and ‘tribal organization’ have the meanings given such terms in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1863).

(6) STATE.—The term ‘State’ means the 50 States and the District of Columbia.

PUBLICATION OF STUDY OF EFFECTIVENESS OF LEVY OF PENALTIES ON HOSPITAL EMPLOYMENT OF PHYSICIANS

Section 4008(c) of Pub. L. 101–508 directed Inspector General of Department of Health and Human Services (acting through Inspector General of Department of Health and Human Services) to conduct a study of the effect of State laws prohibiting the employment of physicians by hospitals on the availability and accessibility of trauma and emergency care services, and include in such study an analysis of the effect of such laws on the ability of hospitals to meet the requirements of section 1887 of the Social Security Act (this section) relating to the examination and treatment of individuals with an emergency medical condition and women in labor, with Secretary to submit a report to Congress on the study not later than 1 year after Nov. 5, 1990.
Subsec. (a). Pub. L. 108–173, §942(a)(2)–(4), inserted subsec. heading, redesignated existing provisions as par. (1), substituted “in this subsection” for “in this section”, and redesignated former subssecs. (b) and (c) as pars. (2) and (3), respectively.


Termination of Advisory Councils
Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, 776, set out in the Appendix to Title 5, Government Organization and Employees.

§1395ff. Determinations; appeals

(a) Initial determinations

(1) Promulgations of regulations
The Secretary shall promulgate regulations and make initial determinations with respect to benefits under part A of this subchapter or part B of this subchapter in accordance with those regulations for the following:

(A) The initial determination of whether an individual is entitled to benefits under such parts.

(B) The initial determination of the amount of benefits available to the individual under such parts.

(C) Any other initial determination with respect to a claim for benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made, for an item or service under such parts, an initial determination made by a utilization and quality control peer review organization under section 1320c–3(a)(2) of this title, and an initial determination made by an entity pursuant to a contract (other than a contract under section 1395w–22 of this title) with the Secretary to administer provisions of this subchapter or subchapter XI of this chapter.

(2) Deadlines for making initial determinations

(A) In general
Subject to subparagraph (B), in promulgating regulations under paragraph (1), initial determinations shall be concluded by not later than the 45-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a claim for benefits—

(i) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) Clean claims
Subparagraph (A) shall not apply with respect to any claim that is subject to the requirements of section 1395h(c)(2) or 1395u(c)(2) of this title.

(3) Redeterminations

(A) In general
In promulgating regulations under paragraph (1) with respect to initial determinations, such regulations shall provide for a fiscal intermediary or a carrier to make a redetermination with respect to a claim for benefits that is denied in whole or in part.

(B) Limitations

(i) Appeal rights
No initial determination may be reconsidered or appealed under subsection (b) of this section unless the fiscal intermediary or carrier has made a redetermination of that initial determination under this paragraph.

(ii) Decisionmaker
No redetermination may be made by any individual involved in the initial determination.

(C) Deadlines

(i) Filing for redetermination
A redetermination under subparagraph (A) shall be available only if notice is filed with the Secretary to request the redetermination by not later than the end of the 120-day period beginning on the date the individual receives notice of the initial determination under paragraph (2).

(ii) Concluding redeterminations
Redeterminations shall be concluded by not later than the 60-day period beginning on the date the fiscal intermediary or the carrier, as the case may be, receives a request for a redetermination. Notice of such determination shall be mailed to the individual filing the claim before the conclusion of such 60-day period.

(D) Construction
For purposes of the succeeding provisions of this section a redetermination under this paragraph shall be considered to be part of the initial determination.

(4) Requirements of notice of determinations
With respect to an initial determination insofar as it results in a denial of a claim for benefits—

(A) the written notice on the determination shall include—

(1) the reasons for the determination, including whether a local medical review policy or a local coverage determination was used;

(2) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and

(3) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section;

(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual.
entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and
(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(5) Requirements of notice of redeterminations

With respect to a redetermination insofar as it results in a denial of a claim for benefits—
(A) the written notice on the redetermination shall include—
(i) the specific reasons for the redetermination;
(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;
(iii) a description of the procedures for obtaining additional information concerning the redetermination; and
(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;
(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both; and
(C) the individual provided such written notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(b) Appeal rights

(1) In general

(A) Reconsideration of initial determination

Subject to subparagraph (D), any individual dissatisfied with any initial determination under subsection (a)(1) of this section shall be entitled to reconsideration of the determination, and, subject to subparagraphs (D) and (E), a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title and, subject to subparagraph (D), any individual shall be entitled to reconsideration of the determination, and, subject to subparagraph (D), any individual may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.

(B) Representation by provider or supplier

(i) In general

Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this section by a person that furnishes or supplies the individual, directly or indirectly, with services or items, solely on the basis that the person furnishes or supplies the individual with such a service or item.

(ii) Mandatory waiver of right to payment from beneficiary

Any person that furnishes services or items to an individual may not represent an individual under this section with respect to the issue described in section 1395pp(a)(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal.

(iii) Prohibition on payment for representation

If a person furnishes services or items to an individual and represents the individual under this section, the person may not impose any financial liability on such individual in connection with such representation.

(iv) Requirements for representatives of a beneficiary

The provisions of section 405(j) of this title and of section 406 of this title (other than subsection (a)(4) of such section) regarding representation of claimants shall apply to representation of an individual with respect to appeals under this section in the same manner as they apply to representation of an individual under those sections.

(C) Succession of rights in cases of assignment

The right of an individual to an appeal under this section with respect to an item or service may be assigned to the provider of services or supplier of the item or service upon the written consent of such individual using a standard form established by the Secretary for such an assignment.

(D) Time limits for filing appeals

(i) Reconsiderations

Reconsideration under subparagraph (A) shall be available only if the individual described in subparagraph (A) files notice with the Secretary to request reconsideration by not later than the end of the 180-day period beginning on the date the individual receives notice of the redetermination under subsection (a)(3) of this section, or within such additional time as the Secretary may allow.

(ii) Hearings conducted by the Secretary

The Secretary shall establish in regulations time limits for the filing of a request for a hearing by the Secretary in accordance with provisions in sections 405 and 406 of this title.

(E) Amounts in controversy

(i) In general

A hearing (by the Secretary) shall not be available to an individual under this section if the amount in controversy is less than $100, and judicial review shall not be available to the individual if the amount in controversy is less than $1,000.

(ii) Aggregation of claims

In determining the amount in controversy, the Secretary, under regulations,
shall allow two or more appeals to be aggregated if the appeals involve—
(I) the delivery of similar or related services to the same individual by one or more providers of services or suppliers, or
(II) common issues of law and fact arising from services furnished to two or more individuals by one or more providers of services or suppliers.

(iii) Adjustment of dollar amounts
For requests for hearings or judicial review made in a year after 2004, the dollar amounts specified in clause (i) shall be equal to such dollar amounts increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount determined under the previous sentence that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(F) Expedited proceedings

(i) Expedited determination
In the case of an individual who has received notice from a provider of services that such provider plans—
(I) to terminate services provided to an individual and a physician certifies that failure to continue the provision of such services is likely to place the individual's health at significant risk, or
(II) to discharge the individual from the provider of services,
the individual may request, in writing or orally, an expedited determination or an expedited reconsideration of an initial determination made under subsection (a)(1) of this section, as the case may be, and the Secretary shall provide such expedited determination or expedited reconsideration.

(ii) Reference to expedited access to judicial review
For the provision relating to expedited access to judicial review, see paragraph (2).

(G) Reopening and revision of determinations
The Secretary may reopen or revise any initial determination or reconsidered determination described in this subsection under guidelines established by the Secretary in regulations.

(2) Expedited access to judicial review

(A) In general
The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, who has filed an appeal under paragraph (1) (other than an appeal filed under paragraph (1)(F)(ii)) may obtain access to judicial review when a review entity (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation for a specific matter in dispute in a case of an appeal.

(B) Prompt determinations
If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review entity that the Departmental Appeals Board does not have the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute, and if such request is accompanied by the documents and materials as the appropriate review entity shall require for purposes of making such determination, such review entity shall make a determination on the request in writing within 60 days after the date such review entity receives the request and such accompanying documents and materials. Such a determination by such review entity shall be considered a final decision and not subject to review by the Secretary.

(C) Access to judicial review

(i) In general
If the appropriate review entity—
(I) determines that there are no material issues of fact in dispute and that the only issues to be adjudicated are ones of law or regulation that the Departmental Appeals Board does not have authority to decide; or
(II) fails to make such determination within the period provided under subparagraph (B),
then the appellant may bring a civil action as described in this subparagraph.

(ii) Deadline for filing
Such action shall be filed, in the case described in—
(I) clause (i)(I), within 60 days of the date of the determination described in such clause; or
(II) clause (i)(II), within 60 days of the end of the period provided under subparagraph (B) for the determination.

(iii) Venue
Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the District Court for the District of Columbia.

(iv) Interest on any amounts in controversy
Where a provider of services or supplier is granted judicial review pursuant to this paragraph, the amount in controversy (if any) shall be subject to annual interest beginning on the first day of the first month
beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of determining reimbursement due providers of services or suppliers under this subchapter.

(D) Review entity defined

For purposes of this subsection, the term "review entity" means an entity of up to three reviewers who are administrative law judges or members of the Departmental Appeals Board selected for purposes of making determinations under this paragraph.

(3) Requiring full and early presentation of evidence by providers

A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c) of this section, unless there is good cause which precluded the introduction of such evidence at or before that reconsideration.

(c) Conduct of reconsiderations by independent contractors

(1) In general

The Secretary shall enter into contracts with qualified independent contractors to conduct reconsiderations of initial determinations made under subparagraphs (B) and (C) of subsection (a)(1) of this section. Contracts shall be for an initial term of three years and shall be renewable on a triennial basis thereafter.

(2) Qualified independent contractor

For purposes of this subsection, the term "qualified independent contractor" means an entity or organization that is independent of any organization under contract with the Secretary that makes initial determinations under subsection (a)(1) of this section, and that meets the requirements established by the Secretary consistent with paragraph (3).

(3) Requirements

Any qualified independent contractor entering into a contract with the Secretary under this subsection shall meet all of the following requirements:

(A) In general

The qualified independent contractor shall perform such duties and functions and assume such responsibilities as may be required by the Secretary to carry out the provisions of this subsection, and shall have sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing to make reconsiderations under this subsection.

(B) Reconsiderations

(i) In general

The qualified independent contractor shall review initial determinations. Where an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title), such review shall include consideration of the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals and any decisions with respect to the reconsideration shall be based on applicable information (including clinical experience (including the medical records of the individual involved) and medical, technical, and scientific evidence.

(ii) Effect of national and local coverage determinations

(I) National coverage determinations

If the Secretary has made a national coverage determination pursuant to the requirements established under the third sentence of section 1395y(a) of this title, such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section.

(II) Local coverage determinations

If the Secretary has made a local coverage determination, such determination shall not be binding on the qualified independent contractor in making a decision with respect to a reconsideration under this section. Notwithstanding the previous sentence, the qualified independent contractor shall consider the local coverage determination in making such decision.

(III) Absence of national or local coverage determination

In the absence of such a national coverage determination or local coverage determination, the qualified independent contractor shall make a decision with respect to the reconsideration based on applicable information, including clinical experience and medical, technical, and scientific evidence.

(C) Deadlines for decisions

(i) Reconsiderations

Except as provided in clauses (iii) and (iv), the qualified independent contractor shall conduct and conclude a reconsideration under subparagraph (B), and mail the notice of the decision with respect to the reconsideration by not later than the end of the 60-day period beginning on the date a request for reconsideration has been timely filed.

(ii) Consequences of failure to meet deadline

In the case of a failure by the qualified independent contractor to mail the notice
of the decision by the end of the period described in clause (i) or to provide notice by the end of the period described in clause (iii), as the case may be, the party requesting the reconsideration or appeal may request a hearing before the Secretary, notwithstanding any requirements for a reconsidered determination for purposes of the party’s right to such hearing.

(iii) Expedited reconsiderations

The qualified independent contractor shall perform an expedited reconsideration under subsection (b)(1)(F) of this section as follows:

(I) Deadline for decision

Notwithstanding section 416(j) of this title and subject to clause (iv), not later than the end of the 72-hour period beginning on the date the qualified independent contractor has received a request for such reconsideration and has received such medical or other records needed for such reconsideration, the qualified independent contractor shall provide notice (by telephone and in writing) to the individual and the provider of services and attending physician of the individual of the results of the reconsideration. Such reconsideration shall be conducted regardless of whether the provider of services or supplier will charge the individual for continued services or whether the individual will be liable for payment for such continued services.

(II) Consultation with beneficiary

In such reconsideration, the qualified independent contractor shall solicit the views of the individual involved.

(III) Special rule for hospital discharges

A reconsideration of a discharge from a hospital shall be conducted under this clause in accordance with the provisions of paragraphs (2), (3), and (4) of section 1320c–3(e) of this title as in effect on the date that precedes December 21, 2000.

(iv) Extension

An individual requesting a reconsideration under this subparagraph may be granted such additional time as the individual specifies (not to exceed 14 days) for the qualified independent contractor to conclude the reconsideration. The individual may request such additional time orally or in writing.

(D) Qualifications for reviewers

The requirements of subsection (g) of this section shall be met (relating to qualifications of reviewing professionals).

(E) Explanation of decision

Any decision with respect to a reconsideration of a qualified independent contractor shall be in writing, be written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include (to the extent appropriate) and shall include a detailed explanation of the decision as well as a discussion of the pertinent facts and applicable regulations applied in making such decision, and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section and in the case of a determination of whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1395y(a)(1)(A) of this title) an explanation of the medical and scientific rationale for the decision.

(F) Notice requirements

Whenever a qualified independent contractor makes a decision with respect to a reconsideration under this subsection, the qualified independent contractor shall promptly notify the entity responsible for the payment of claims under part A of this subchapter or part B of this subchapter of such decision.

(G) Dissemination of decisions on reconsiderations

Each qualified independent contractor shall make available all decisions with respect to reconsiderations of such qualified independent contractors to fiscal intermediaries (under section 1395h of this title), carriers (under section 1395u of this title), peer review organizations (under part B of subchapter XI of this chapter), Medicare+Choice organizations offering Medicare+Choice plans under part C of this subchapter, other entities under contract with the Secretary to make initial determinations under part A of this subchapter or part B of this subchapter or subchapter XI of this chapter, and to the public. The Secretary shall establish a methodology under which qualified independent contractors shall carry out this subparagraph.

(II) Ensuring consistency in decisions

Each qualified independent contractor shall monitor its decisions with respect to reconsiderations to ensure the consistency of such decisions with respect to requests for reconsideration of similar or related matters.

(I) Data collection

(i) In general

Consistent with the requirements of clause (ii), a qualified independent contractor shall collect such information relevant to its functions, and keep and maintain such records in such form and manner as the Secretary may require to carry out the purposes of this section and shall permit access to and use of any such information and records as the Secretary may require for such purposes.

(ii) Type of data collected

Each qualified independent contractor shall keep accurate records of each deci-

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2So in original. The word “and” probably should not appear.
3So in original. A comma probably should appear.
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Section 1395ff, consistent with standards established by the Secretary for such purpose. Such records shall be maintained in an electronic database in a manner that provides for identification of the following:

(i) Specific claims that give rise to appeals.

(ii) Situations suggesting the need for increased education for providers of services, physicians, or suppliers.

(iii) Situations suggesting the need for changes in national or local coverage determinations.

(iv) Situations suggesting the need for changes in local coverage determinations.

(iii) Annual reporting
Each qualified independent contractor shall submit annually to the Secretary (or otherwise as the Secretary may request) records maintained under this paragraph for the previous year.

(J) Hearings by the Secretary
The qualified independent contractor shall (i) submit such information as is required for an appeal of a decision of the contractor, and (ii) participate in such hearings as required by the Secretary.

(K) Independence requirements
(i) In general
Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity—

(I) is not a related party (as defined in subsection (g)(5) of this section);

(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

(III) does not otherwise have a conflict of interest with such a party.

(ii) Exception for reasonable compensation
Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).

(iii) Limitations on entity compensation
Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional.

(4) Number of qualified independent contractors
The Secretary shall enter into contracts with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection.

(5) Limitation on qualified independent contractor liability
No qualified independent contractor having a contract with the Secretary under this subsection and no person who is employed by, or who has a fiduciary relationship with, any such qualified independent contractor or who furnishes professional services to such qualified independent contractor, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this subsection or to a valid contract entered into under this subsection, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(d) Deadlines for hearings by the Secretary; notice
(1) Hearing by administrative law judge
(A) In general
Except as provided in subparagraph (B), an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor under subsection (c) of this section and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing has been timely filed.

(B) Waiver of deadline by party seeking hearing
The 90-day period under subparagraph (A) shall not apply in the case of a motion or stipulation by the party requesting the hearing to waive such period.

(2) Departmental Appeals Board review
(A) In general
The Departmental Appeals Board of the Department of Health and Human Services shall conduct and conclude a review of the decision on a hearing described in paragraph (1) and make a decision or remand the case to the administrative law judge for reconsideration by not later than the end of the 90-day period beginning on the date a request for review has been timely filed.

(B) DAB hearing procedure
In reviewing a decision on a hearing under this paragraph, the Departmental Appeals Board shall review the case de novo.

(3) Consequences of failure to meet deadlines
(A) Hearing by administrative law judge
In the case of a failure by an administrative law judge to render a decision by the end of the period described in paragraph (1), the party requesting the hearing may request a review by the Departmental Appeals Board of the Department of Health and Human Services, notwithstanding any requirements for a hearing for purposes of the party’s right to such a review.

(B) Departmental Appeals Board review
In the case of a failure by the Departmental Appeals Board to render a decision by the end of the period described in paragraph (2), the party requesting the hearing may seek judicial review, notwithstanding any requirements for a hearing for purposes of the party’s right to such judicial review.
(4) Notice
Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include—
(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);
(B) the procedures for obtaining additional information concerning the decision; and
(C) notification of the right to appeal the decision and instructions on how to initiate such an appeal under this section.

(e) Administrative provisions

(1) Limitation on review of certain regulations
A regulation or instruction that relates to a method for determining the amount of payment under part B of this subchapter and that was initially issued before January 1, 1981, shall not be subject to judicial review.

(2) Outreach
The Secretary shall perform such outreach activities as are necessary to inform individuals entitled to benefits under this subchapter and providers of services and suppliers with respect to their rights of, and the process for, appeals made under this section. The Secretary shall use the toll-free telephone number maintained by the Secretary under section 1395b–2(b) of this title to provide information regarding appeal rights and respond to inquiries regarding the status of appeals.

(3) Continuing education requirement for qualified independent contractors and administrative law judges
The Secretary shall provide to each qualified independent contractor, and, in consultation with the Commissioner of Social Security, to administrative law judges that decide appeals made under this subchapter or enrolled under part B of this subchapter, continuing education with respect to their rights of, and the process for, appeals made under this section. The Secretary determines appropriate.

(4) Reports
(A) Annual report to Congress
The Secretary shall submit to Congress an annual report describing the number of appeals for the previous year, identifying issues that require administrative or legislative actions, and including any recommendations of the Secretary with respect to such actions. The Secretary shall include in such report an analysis of determinations by qualified independent contractors with respect to inconsistent decisions and an analysis of the causes of any such inconsistencies.
(B) Survey
Not less frequently than every 5 years, the Secretary shall conduct a survey of a valid sample of individuals entitled to benefits under this subchapter who have filed appeals of determinations under this section, providers of services, and suppliers to determine the satisfaction of such individuals or entities with the process for appeals of determinations provided for under this section and education and training provided by the Secretary with respect to that process. The Secretary shall submit to Congress a report describing the results of the survey, and shall include any recommendations for administrative or legislative actions that the Secretary determines appropriate.

(f) Review of coverage determinations

(1) National coverage determinations

(A) In general
Review of any national coverage determination shall be subject to the following limitations:
(i) Such a determination shall not be reviewed by any administrative law judge.
(ii) Such a determination shall not be held unlawful or set aside on the ground that a requirement of section 553 of title 5 or section 1395hh(b) of this title, relating to publication in the Federal Register or opportunity for public comment, was not satisfied.
(iii) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services. In conducting such a review, the Departmental Appeals Board—
(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the Board determines that the record is incomplete or lacks adequate information to support the validity of the determination;
(II) may, as appropriate, consult with appropriate scientific and clinical experts; and
(III) shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.
(iv) The Secretary shall implement a decision of the Departmental Appeals Board within 30 days of receipt of such decision.
(v) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) Definition of national coverage determination
For purposes of this section, the term “national coverage determination” means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this subchapter or a determination with respect to the amount of payment made for a particular item or service so covered.
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(2) Local coverage determination

(A) In general

Review of any local coverage determination shall be subject to the following limitations:

(i) Upon the filing of a complaint by an aggrieved party, such a determination shall be reviewed by an administrative law judge. The administrative law judge—

(ii) shall issue a national noncoverage determination, with or without limitations.

(B) Deemed action by the Secretary

In the case of an action described in subparagraph (A)(iv), if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in subparagraph (A)(iii) as of the deadline.

(C) Explanation of determination

When issuing a determination under subparagraph (A), the Secretary shall include an explanation of the basis for the determination.

(3) No material issues of fact in dispute

In the case of a determination that may otherwise be subject to review under paragraph (1)(A)(iii) or paragraph (2)(A)(i), where the moving party alleges that—

(A) there are no material issues of fact in dispute, and

(B) the only issue of law is the constitutionality of a provision of this subchapter, or that a regulation, determination, or ruling by the Secretary is invalid, the moving party may seek review by a court of competent jurisdiction without filing a complaint under such paragraph and without otherwise exhausting other administrative remedies.

(4) Pending national coverage determinations

(A) In general

In the event the Secretary has not issued a national coverage or noncoverage determination with respect to a particular type or class of items or services, an aggrieved person (as described in paragraph (5)) may submit to the Secretary a request to make such a determination with respect to such items or services. By not later than the end of the 90-day period beginning on the date the Secretary receives such a request (notwithstanding the receipt by the Secretary of new evidence (if any) during such 90-day period), the Secretary shall take one of the following actions:

(i) Issue a national coverage determination, with or without limitations.

(ii) Issue a national noncoverage determination.

(iii) Issue a determination that no national coverage or noncoverage determination is appropriate as of the end of such 90-day period with respect to national coverage of such items or services.

(iv) Issue a notice that states that the Secretary has not completed a review of the request for a national coverage determination and that includes an identification of the remaining steps in the Secretary’s review process and a deadline by which the Secretary will complete the review and take an action described in clause (i), (ii), or (iii).

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(B) Deemed action by the Secretary

In the case of an action described in subparagraph (A)(iv), if the Secretary fails to take an action referred to in such clause by the deadline specified by the Secretary under such clause, then the Secretary is deemed to have taken an action described in subparagraph (A)(iii) as of the deadline.

(C) Explanation of determination

When issuing a determination under subparagraph (A), the Secretary shall include an explanation of the basis for the determination.

An action taken under subparagraph (A) (other than clause (iv)) is deemed to be a national coverage determination for purposes of review under paragraph (1)(A).

(5) Standing

An action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under part A of this subchapter, or enrolled under part B of this subchapter, or both, who are in need of the items or services that are the subject of the coverage determination.

(6) Publication on the Internet of decisions of hearings of the Secretary

Each decision of a hearing by the Secretary with respect to a national coverage determination shall be made public, and the Secretary shall publish each decision on the Medicare Internet site of the Department of Health and Human Services. The Secretary shall remove from such decision any information that

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would identify any individual, provider of services, or supplier.

(7) Annual report on national coverage determinations

(A) In general

Not later than December 1 of each year, beginning in 2001, the Secretary shall submit to Congress a report that sets forth a detailed compilation of the actual time periods that were necessary to complete and fully implement national coverage determinations that were made in the previous fiscal year for items, services, or medical devices not previously covered as a benefit under this subchapter, including, with respect to each new item, service, or medical device, a statement of the time taken by the Secretary to make and implement the necessary coverage, coding, and payment determinations, including the time taken to complete each significant step in the process of making and implementing such determinations.

(B) Publication of reports on the Internet

The Secretary shall publish each report submitted under clause (i) on the medicare Internet site of the Department of Health and Human Services.

(8) Construction

Nothing in this subsection shall be construed as permitting administrative or judicial review pursuant to this section insofar as such review is explicitly prohibited or restricted under another provision of law.

(g) Qualifications of reviewers

(1) In general

In reviewing determinations under this section, a qualified independent contractor shall assure that—

(A) each individual conducting a review shall meet the qualifications of paragraph (2);

(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

(C) in the case of a review by a panel described in subsection (c)(3)(B) of this section composed of physicians or other health care professionals (each in this subsection referred to as a “reviewing professional”), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), a reviewing professional shall be a physician (allopathic or osteopathic).

(2) Independence

(A) In general

Subject to subparagraph (B), each individual conducting a review in a case shall—

(i) not be a related party (as defined in paragraph (5));

(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

(iii) not otherwise have a conflict of interest with such a party.

(B) Exception

Nothing in subparagraph (A) shall be construed to—

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if—

(I) the individual is not involved in the provision of items or services in the case under review;

(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, or such individual’s authorized representative, and neither party objects; and

(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor;

(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with paragraph (3).

For purposes of this paragraph, the term “participation agreement” means an agreement relating to the provision of health care services by the individual and does not include the provision of services as a reviewer under this subsection.

(3) Limitations on reviewer compensation

Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the reviewer.

(4) Licensure and expertise

Each reviewing professional shall be—

(A) a physician (allopathic or osteopathic) who is appropriately credentialied or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

(5) Related party defined

For purposes of this section, the term “related party” means, with respect to a case
under this subchapter involving a specific individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, any of the following:

(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

(B) The individual (or authorized representative).

(C) The health care professional that provides the items or services involved in the case.

(D) The institution at which the items or services (or treatment) involved in the case are provided.

(E) The manufacturer of any drug or other item that is included in the Items or services involved in the case.

(F) Any other party determined under any regulations to have a substantial interest in the case involved.

(h) Prior determination process for certain items and services

(1) Establishment of process

(A) In general

With respect to a medicare administrative contractor that has a contract under section 1395k–1 of this title that provides for making payments under this subchapter with respect to physicians’ services (as defined in section 1395w–4(j)(3) of this title), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

(B) Eligible requester

For purposes of this subsection, each of the following shall be an eligible requester:

(i) A participating physician, but only with respect to physicians’ services furnished to an individual who is entitled to benefits under this subchapter and who has consented to the physician making the request under this subsection for those physicians’ services.

(ii) An individual entitled to benefits under this subchapter, but only with respect to a physicians’ service for which the individual receives, from a physician, an advance beneficiary notice under section 1395pp(a) of this title.

(2) Secretarial flexibility

The Secretary shall establish by regulation reasonable limits on the physicians’ services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the physicians’ service, administrative costs and burdens, and other relevant factors.

(3) Request for prior determination

(A) In general

Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination, before the furnishing of a physicians’ service, as to whether the physicians’ service is covered under this subchapter consistent with the applicable requirements of section 1395y(a)(1)(A) of this title (relating to medical necessity).

(B) Accompanying documentation

The Secretary may require that the request be accompanied by a description of the physicians’ service, supporting documentation relating to the medical necessity for the physicians’ service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (A)(i), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

(4) Response to request

(A) In general

Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

(i) the physicians’ service is so covered; or

(ii) the physicians’ service is not so covered.

(B) Contents of notice for certain determinations

(i) Noncoverage

If the contractor makes the determination described in subparagraph (A)(i), the contractor shall include in the notice a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and a description of any applicable rights under subsection (a) of this section.

(ii) Insufficient information

If the contractor makes the determination described in subparagraph (A)(ii), the contractor shall include in the notice a description of the additional information required to make the coverage determination.

(C) Deadline to respond

Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection (a) of this section.

(D) Informing beneficiary in case of physician request

In the case of a request by a participating physician under paragraph (1)(B)(i), the process shall provide that the individual to whom the physicians’ service is proposed to be furnished shall be informed of any determination described in subparagraph (A)(ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the physicians’ service and have a claim submitted for the physicians’ service.
(5) **Binding nature of positive determination**

If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

(6) **Limitation on further review**

(A) **In general**

Contractor determinations described in paragraph (4)(A)(i) or (4)(A)(ii) (relating to pre-service claims) are not subject to further administrative appeal or judicial review under this section or otherwise.

(B) **Decision not to seek prior determination or negative determination does not impact right to obtain services, seek reimbursement, or appeal rights**

Nothing in this subsection shall be construed as affecting the right of an individual who—

(1) decides not to seek a prior determination under this subsection with respect to physicians’ services; or

(ii) seeks such a determination and has received a determination described in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such physicians’ services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to physicians’ service shall not be taken into account in such administrative or judicial review.

(C) **No prior determination after receipt of services**

Once an individual is provided physicians’ services, there shall be no prior determination under this subsection with respect to such physicians’ services.

(i) **Mediation process for local coverage determinations**

(1) **Establishment of process**

The Secretary shall establish a mediation process under this subsection through the use of a physician trained in mediation and employed by the Centers for Medicare & Medicaid Services.

(2) **Responsibility of mediator**

Under the process established in paragraph (1), such a mediator shall mediate in disputes between groups representing providers of services, suppliers (as defined in section 1395x(d) of this title), and the medical director for a medicare administrative contractor whenever the regional administrator (as defined by the Secretary) involved determines that there was a systematic pattern and a large volume of complaints from such groups regarding decisions of such director or there is a complaint from the co-chair of the advisory committee for that contractor to such regional administrator regarding such dispute.


**REFERENCES IN TEXT**

Parts A, B, and C of this subchapter, referred to in text, are classified to sections 1395c et seq., 1395j et seq., and 1399w–21 et seq., respectively, of this title.

Part B of subchapter XI of this chapter, referred to in subsecs. (c)(3)(G) and (e)(3), is classified to section 1395c–4 et seq. of this title.

**AMENDMENTS**


Subsec. (a)(4), (5). Pub. L. 108–173, §933(c)(1), added pars. (4) and (5).

Subsec. (b)(1)(A). Pub. L. 108–173, §932(a)(1)(A), inserted “; subject to paragraph (2),” before “to judicial review of the Secretary’s final decision”.


Subsec. (c)(3)(A). Pub. L. 108–173, §933(d)(1)(A), substituted “sufficient medical, legal, and other expertise (including knowledge of the program under this subchapter) and sufficient staffing” for “sufficient training and expertise in medical science and legal matters”.


Subsec. (c)(3)(D). Pub. L. 108–173, §933(d)(2)(A), amended heading and text of subpar. (D) generally, substituting provisions directing that subsec. (g) requirements be met for provisions prohibiting a physician or health care professional from reviewing a determination where such physician or health care professional had been directly responsible for furnishing services or had had a significant financial interest in the institution, organization, or agency which provided the services.

Subsec. (c)(3)(E). Pub. L. 108–173, §933(c)(2), inserted “be written in a manner calculated to be understood by the individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and shall include (to the extent appropriate)” after “in writing” and “and a notification of the right to appeal such determination and instructions on how to initiate such appeal under this section” after “such decision.”.
§ 1395ff


Subsec. (c)(3)(J)(I). Pub. L. 108–173, § 933(c)(4), substituted “submit” for “prepare” and struck out “with respect to a reconsideration to the Secretary for a hearing, including as necessary, explanations of issues involved in the decision and relevant policies” after “determination of the contractor”.


Subsec. (d). Pub. L. 108–173, § 933(d)(3), inserted “a sufficient number of qualified independent contractors (but no fewer than 4 such contractors) to conduct reconsiderations consistent with the timeframes applicable under this subsection” for “not fewer than 12 qualified independent contractors under this subsection”.


Subsec. (f)(4)(A)(iv). Pub. L. 108–173, § 498(c)(1), substituted “clause (i), (ii), or (iii)” for “subclause (I), (II), or (III)”.


2000—Pub. L. 106–554, § 1(a)(6) [title V, § 521(a)], added section.

Subsec. (b)(1). Pub. L. 99–509, § 9313(a)(1), in concluding provisions, inserted at end “Sections 406(a), 1302, and 1395hh of this title shall not be construed as authorizing the Secretary to prohibit an individual from being represented under this subsection by a person that furnishes or supplies the individual, directly or indirectly, with services or items solely on the basis that the person furnishes or supplies the individual with such a service or item. Any person that furnishes services or items to an individual may not represent an individual under this subsection with respect to the issue described in section 1395ppa(2) of this title unless the person has waived any rights for payment from the beneficiary with respect to the services or items involved in the appeal. If a person furnishes services or items to an individual and represents the individual under this subsection, the person may not impose any financial liability on such individual in connection with such representation.”


Subsec. (b)(2). Pub. L. 99–509, § 9314(a)(1)(C), amended par. (2) generally. Prior to amendment, par. (2) read as follows: “Notwithstanding the provisions of subparagraph (C) of paragraph (1) of this subsection, a hearing shall not be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $100; nor shall judicial review be available to an individual by reason of such subparagraph (C) if the amount in controversy is less than $1,000.”


1984—Subsec. (b)(1)(B). Pub. L. 98–369 struck out the comma before “or section 1395i–2” and struck out “,” or section 1819” after “section 1395l of this title”.

1972—Subsec. (b). Pub. L. 92–603 redesignated existing provisions as par. (1), generally amended conditions under which a dissatisfied individual shall be entitled to a hearing by Secretary and to judicial review of final decision of Secretary after such hearing, and added par. (2).

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the transition provided by the Secretary of Health and Human Services in the use of those terms, see section 422(h)(2) of the Balanced Budget Act of 1997, set out as a note under section 1512 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT


EFFECTIVE DATE OF 2001 AMENDMENT


EFFECTIVE DATE OF 2000 AMENDMENT

under such process filed not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003].

(2) SUNSET.—Such prior determination process shall not apply to requests filed after the end of the 5-year period beginning on the first date on which requests for determinations under such process are accepted.

(3) TRANSITION.—During the period in which the amendment made by subsection (a) [amending this section] has become effective but contracts are not provided under section 1874A of the Social Security Act [section 1385kk-1 of this title] with medicare administrative contractors, any reference in section 1869(g) [probably should be 1869(h)] of such Act [subsec. (h) of this section] (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of such Act [sections 1395h and 1395u of this title].

(4) LIMITATION ON APPLICATION TO SUB.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment made by subsection (a) [amending this section] shall not be considered to have a change in law or regulation.

Amendment by section 948(b)(1), (c) of Pub. L. 108–173 effective, except as otherwise provided, as if included in the enactment of the BIPA [the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2003, P.L. 108–173, as enacting section 1314(a) of Public Law 106–554], see section 948(e) of Pub. L. 108–173, set out as a note under section 1314 of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1999, 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 1395s of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by 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 1395s of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–296 effective Mar. 31, 1995, 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. 103–296, set out as a note under section 1395s of this title.

EFFECTIVE DATE OF 1998 AMENDMENT

Section 9341(b) of Pub. L. 99–509 provided that: “The amendments made by subsection (a) [amending this section and sections 1395u and 1395p of this title] shall apply to items and services furnished on or after Jan. 1, 1987.”

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Section 2990(b) of Pub. L. 92–603 provided that:

“(1) The provisions of subparagraphs (A) and (B) of section 1869(b)(1) of the Social Security Act [subsec. (b)(1)(A), (B) of this section], as amended by subsection (a) of this section, shall be effective on the date of enactment of this Act [Oct. 30, 1972].

“(2) The provisions of paragraph (2) and subparagraph (C) of paragraph (1) of section 1869(b) of the Social Security Act [subsec. (b)(1)(C) and (b)(2) of this section], as amended by subsection (a) of this section, shall be effective with respect to any claims under part A of title XVIII of such Act [part A of this subchapter], filed—

“(A) in or after the month in which this Act is enacted [Oct. 1972], or

“(B) before the month in which this Act is enacted [Oct. 1972], but only if a civil action with respect to a final decision of the Secretary of Health, Education, and Welfare on such claim has not been commenced under such section 1869(b) [subsec. (b) of this section] before such month.”

TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS


“(a) TRANSITION PLAN.—

“(1) IN GENERAL.—Not later than April 1, 2004, the Commissioner of Social Security and the Secretary of Health and Human Services shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act [this subchapter] (and related provisions in title XI of such Act [subchapter XI of this chapter]) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Services.

“(2) CONTENTS.—The plan shall include information on the following:

“(A) WORKLOAD.—The number of such administrative law judges and support staff required now and in the future to hear and decide such cases in a timely manner, taking into account the current and anticipated claims volume, appeals, number of beneficiaries, and statutory changes.

“(B) COST PROJECTIONS AND FINANCING.—Funding levels required for fiscal year 2005 and subsequent fiscal years to carry out the functions transferred under the plan.

“(C) TRANSITION TIMETABLE.—A timetable for the transition.

“(D) REGULATIONS.—The establishment of specific regulations to govern the appeals process.

“(E) CASE TRACKING.—The development of a unified case tracking system that will facilitate the maintenance and transfer of case specific data across both the fee-for-service and managed care components of the medicare program.

“(F) FEASIBILITY OF PRECEDENTIAL AUTHORITY.—

“The feasibility of developing a process to give decisions of the Departmental Appeals Board in the Department of Health and Human Services addressing broad legal issues binding, precedential authority.
(G) Access to Administrative Law Judges.—The feasibility of—

(i) filing appeals with administrative law judges electronically; and

(ii) conducting hearings using tele- or video-conference technologies.

(H) Independence of Administrative Law Judges.—The steps that shall be taken to ensure the independence of administrative law judges consistent with the requirements of subsection (b)(2).

(I) Geographic Distribution.—The steps that should be taken to provide for an appropriate geographic distribution of administrative law judges throughout the United States to carry out subsection (b)(3).

(J) Hiring.—The steps that should be taken to hire administrative law judges (and support staff) to carry out subsection (b)(4).

(K) Performance Standards.—The appropriateness of establishing performance standards for administrative law judges with respect to timelines for decisions in cases under title XVIII of the Social Security Act (this subchapter) taking into account requirements under subsection (b)(2) for the independence of such judges and consistent with the applicable provisions of title 5, United States Code[, relating to impartiality.

(L) Shared Resources.—The steps that should be taken to carry out subsection (b)(6) (relating to the arrangements with the Commissioner of Social Security to share office space, support staff, and other resources, with appropriate reimbursement).

(M) Training.—The training that should be provided to administrative law judges with respect to laws and regulations under title XVIII of the Social Security Act (this subchapter).

(3) ADDITIONAL INFORMATION.—The plan may also include recommendations for further congressional action, including modifications to the requirements and deadlines established under section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act).

(4) GAO Evaluation.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) Transfer of Adjudication Authority.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Administration to the Secretary.

(2) ASSURING INDEPENDENCE OF JUDGES.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report to, or be subject to supervision by, another officer of the Department of Health and Human Services.

(3) Geographic Distribution.—The Secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout the United States to ensure timely access to such judges.

(4) Hiring Authority.—Subject to the amounts provided in advance in appropriations Acts, the Secretary shall have authority to hire administrative law judges to hear such cases, taking into consideration those judges with expertise in handling Medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) Financing.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become payable to the Secretary for the functions so transferred.

(6) Shared Resources.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) Increased Financial Support.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (42 U.S.C. 1395ff) (as amended by this Act), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund, established under section 1817 of the Social Security Act (42 U.S.C. 1395f), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395f)) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to—

(1) increase the number of administrative law judges (and their staffs) under subsection (b)(4); and

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

TRANSITION


(a) Claims.—The Secretary [of Health and Human Services] shall develop, in consultation with appropriate Medicare contractors (as defined in section 1869(g) of the Social Security Act [section 1395zzg of this title], as inserted by section 301(a)(1) of Pub. L. 108–173, title IX, § 933(d)(5), Dec. 8, 2003, 117 Stat. 2412, provided that: "In applying section 1395zzg of the Social Security Act [this subchapter], a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) Deadline.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall first develop the process under subsection (a)."

STUDY OF AGGREGATION RULE FOR CLAMS FOR SIMILAR PHYSICIANS’ SERVICES

Pub. L. 101–508, title IV, § 4113, Nov. 5, 1990, 104 Stat. 1388–64, directed Secretary of Health and Human Services to carry out a study of the effects of permitting the aggregation of claims that involve common issues of law and fact furnished in the same carrier area to two or more individuals by two or more physicians within the same 12-month period for purposes of ap-
payments provided for under subsec. (b)(2) of this section, and to report on the results of such study and any recommendations to Congress by Dec. 31, 1992.

Medicare Hearings and Appeals

Section 4037 of Pub. L. 100–203 provided that:

(a) Maintaining current system for hearings and appeals—Any hearing conducted under section 1869(b)(1) of the Social Security Act [subsec. (b)(1) of this section] prior to the earliest of the date on which the Secretary of Health and Human Services submits the report required to be submitted by the Secretary under subsection (b)(1) or September 1 shall be conducted by Administrative Law Judges of the Office of Hearings and Appeals of the Social Security Administration in the same manner as are hearings conducted under section 205(b)(1) of such Act [section 405(b)(1) of this title].

(b) Study and report on use of telephone hearings.—

"(1) The Secretary of Health and Human Services and the Comptroller General of the United States shall each conduct a study on holding hearings under section 1869(b)(1) of the Social Security Act [subsec. (b)(1) of this section] by telephone and shall each report the results of the study not later than 6 months after the date of enactment of this Act [Dec. 22, 1987].

"(2) The studies under paragraph (1) shall focus on whether telephone hearings allow for a full and fair evidentiary hearing, in general, or with respect to any particular category of claims and shall examine the possible improvements to the hearing process (such as cost-effectiveness, convenience to the claimant, and reduction in time under the process) resulting from the use of such hearings as compared to the adoption of other changes to the process (such as expansions in staff and resources)."

§ 1395gg. Overpayment on behalf of individuals and settlement of claims for benefits on behalf of deceased individuals

(a) Payments to providers of services or other person regarded as payment to individuals

Any payment under this subchapter to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

(b) Incorrect payments on behalf of individuals; payment adjustment

Where—

(1) more than the correct amount is paid under this subchapter to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, within such period as he may specify, the excess over the correct amount cannot be recouped from such provider of services or other person, or (B) that such provider of services or other person was without fault with respect to the payment of such excess over the correct amount, or

(2) any payment has been made under section 1395f(e) of this title to a provider of services or other person for items or services furnished an individual, proper adjustments shall be made, under regulations prescribed (after consultation with the Railroad Retirement Board) by the Secretary, by decreasing subsequent payments—

(3) to which such individual is entitled under subchapter II of this chapter or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], as the case may be, or

(4) if such individual dies before such adjustment has been completed, to which any other individual is entitled under subchapter II of this chapter or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.], as the case may be, with respect to the wages and self-employment income or the compensation constituting the basis of the benefits of such deceased individual under subchapter II of this chapter.

As soon as practicable after any adjustment under paragraph (3) or (4) is determined to be necessary, the Secretary, for purposes of this section, section 1395t(f) of this title, and section 1395y(a) of this title, shall certify to the Railroad Retirement Board if the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.] the amount of the overpayment as to which the adjustment is to be made.

For purposes of clause (B) of paragraph (1), such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary’s determination that more than such correct amount was paid subsequent to the third year following the year in which notice was sent to such individual that such amount had been paid; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter.

(c) Exception to subsection (b) payment adjustment

There shall be no adjustment as provided in subsection (b) of this section (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1395f(e) of this title) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4) of this section, if such adjustment (or recovery) would defeat the purposes of subchapter II of subchapter XVIII of this title or would be against equity and good conscience.

Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this subchapter) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this subchapter by reason of the provisions of paragraph (1) or (9) of section 1395y(a) of this title and (B) if the Secretary’s determination that such payment was incorrect was made subsequent to the third year following the year in which notice of such payment was sent to such individual; except that the Secretary may reduce such three-year period to not less than one year if he finds such reduction is consistent with the objectives of this subchapter.

(d) Liability of certifying or disbursing officer for failure to recoup

No certifying or disbursing officer shall be held liable for any amount certified or paid by
him to any provider of services or other person where the adjustment or recovery of such amount is waived under subsection (c) of this section or where adjustment under subsection (b) of this section is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

(e) Settlement of claims for benefits under this subchapter on behalf of deceased individuals

If an individual, who received services for which payment may be made to such individual under this subchapter, dies, and payment for such services was made (other than under this subchapter), and the individual died before any payment due him under this subchapter with respect to such services was completed, payment of the amount due (including the amount of any unnegotiated checks) shall be made—

(1) if the payment for such services was made (before or after such individual’s death) by a person other than the deceased individual, to the person or persons determined by the Secretary under regulations to have paid for such services, or if the payment for such services was made by the deceased individual before his death, to the legal representative of the estate of such deceased individual, if any;

(2) if there is no person who meets the requirements of paragraph (1), to the person, if any, who is determined by the Secretary to be the surviving spouse of the deceased individual and who was either living in the same household with the deceased at the time of his death or was, for the month in which the deceased individual died, entitled to a monthly benefit on the basis of the same wages and self-employment income as was the deceased individual;

(3) if there is no person who meets the requirements of paragraph (1) or (2), or if the person who meets such requirements died before the payment due him under this subchapter is completed, to the child or children, if any, of the deceased individual who were, for the month in which the deceased individual died, entitled to monthly benefits on the basis of the same wages and self-employment income as was the deceased individual (and, in case there is more than one such child, in equal parts to each such child);

(4) if there is no person who meets the requirements of paragraph (1), (2), or (3), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the parent or parents, if any, of the deceased individual who were, for the month in which the deceased individual died, entitled to monthly benefits on the basis of the same wages and self-employment income as was the deceased individual (and, in case there is more than one such parent, in equal parts to each such parent);

(5) if there is no person who meets the requirements of paragraph (1), (2), (3), or (4), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the surviving spouse of the deceased individual;

(6) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), or (5), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the person or persons, if any, determined by the Secretary to be the child or children of the deceased individual (and, in case there is more than one such child, in equal parts to each such child);

(7) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), (5), or (6), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the parent or parents, if any, of the deceased individual (and, in case there is more than one such parent, in equal parts to each such parent); or

(8) if there is no person who meets the requirements of paragraph (1), (2), (3), (4), (5), (6), or (7), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, to the legal representatives of the estate of the deceased individual, if any.

(f) Settlement of claims for section 1395k benefits on behalf of deceased individuals

If an individual who received medical and other health services for which payment may be made under section 1395k(a)(1) of this title dies, and no assignment of the right to payment for such services was made by such individual before his death, and payment for such services has not been made—

(1) if the person or persons who furnished the services agree to the terms of assignment specified in section 1395u(b)(3)(B)(ii) of this title with respect to the services, payment for such services shall be made to such person or persons, and

(2) if the person or persons who furnished the services do not agree to the terms of assignment specified in section 1395u(b)(3)(B)(ii) of this title with respect to the services, payment for such services shall be made on the basis of an itemized bill to the person who has agreed to assume the legal obligation to make payment for such services and files a request for payment (with such accompanying evidence of such legal obligation as may be required in regulations), but only in such amount and subject to such conditions as would be applicable if the individual who received the services had not died.

(g) Refund of premiums for deceased individuals

If an individual, who is enrolled under section 1395i-2(c) of this title or under section 1395p of this title, dies, and premiums with respect to such enrollment have been received with respect to such individual for any month after the month of his death, such premiums shall be refunded to the person or persons determined by the Secretary under regulations to have paid such premiums or if payment for such premiums was made by the deceased individual before his death, to the legal representative of the estate of such deceased individual, if any. If there is no person who meets the requirements of the preceding sentence such premiums shall be refunded to the person or persons in the priorities specified in paragraphs (2) through (7) of subsection (e) of this section.
(h) Appeals by providers of services or suppliers

Notwithstanding subsection (f) of this section or any other provision of law, the Secretary shall permit a provider of services or supplier to appeal any determination of the Secretary under this subchapter relating to services rendered under this subchapter to an individual who subsequently dies if there is no other party available to appeal such determination.


REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (b), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, §101, Oct. 16, 1974, 88 Stat. 1305, which is classified generally to subchapter IV (§121 et seq.) of chapter 9 of Title 45, Railroads. For further details and complete classification of this Act to the Code, see Codification note set out preceding section 231 of Title 45, section 231 of Title 45, and Tables.

AMENDMENTS


Subsec. (f)(1), (2), Pub. L. 100–360, §411(j)(4)(B), substituted ‘‘of assignment specified in’’ for ‘‘specified in subclauses (I) and (II) of’’.


Subsec. (f)(1), (2). Pub. L. 100–203, §4096(a)(2), substituted ‘‘to the terms specified in subclauses (I) and (II) of section 1395c(h)(3) of this title with respect to the services’’ for ‘‘that the reasonable charge is the full charge for the services’’.

1982—Subsec. (c). Pub. L. 97–248 substituted ‘‘section 1395y(a)’’ for ‘‘section 1395y’’.

1980—Subsec. (f). Pub. L. 96–499 amended subsec. (f) generally, inserting provision for payments to providers of medical and other health services where the person or persons furnishing the services did not agree that the reasonable charge was the full charge for such services.


1972—Subsec. (b). Pub. L. 92–403, §281(a), required that provider of services or other person be without fault with respect to payment of excess over correct amount as prerequisite to adjustment or recovery of incorrect payments.

Subsec. (c). Pub. L. 92–403, §§261(a), 281(b), substituted ‘‘or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4) of this section, if, ‘‘for ‘‘and where’’, inserted reference to subchapter XVII of this chapter, and inserted provisions covering the adjustment or recovery of incorrect payments against individuals who are without fault.

Subsec. (g). Pub. L. 92–603, §266, added subsec. (g).

1968—Pub. L. 90–248, §154(b), provided for settlement of claims for benefits on behalf of deceased individuals in section catchline.

Subsecs. (e), (f). Pub. L. 90–248, §154(c), added subsecs. (e) and (f).

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title IX, §939(b), Dec. 8, 2003, 117 Stat. 2416, provided that: ‘‘The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003] and shall apply to items and services furnished on or after such date.’’

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title I, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by section 4096(a)(2) of Pub. L. 100–203 applicable to services furnished on or after Jan. 1, 1988, see section 4096(d) of Pub. L. 100–203, set out as a note under section 1320c–3 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT


EFFECTIVE DATE OF 1980 AMENDMENT

Section 954(b) of Pub. L. 96–499 provided that: ‘‘The amendment made by this section [amending this section] shall apply only to claims filed on or after January 1, 1981.’’

EFFECTIVE DATE OF 1974 AMENDMENT


EFFECTIVE DATE OF 1972 AMENDMENT

Section 261(b) of Pub. L. 92–603 provided that: ‘‘The amendment made by subsection (a) [amending this section] shall apply with respect to notices sent to individuals after the date of the enactment of this Act [Oct. 30, 1972].’’

Section 261(g) of Pub. L. 92–603 provided that: ‘‘The provisions of subsection (a)(1) [amending this section] shall apply with respect to notices of payment sent to individuals after the date of enactment of this Act [Oct. 30, 1972].’’

WAIVER OF LIABILITY LIMITING RECOUPMENT IN CERTAIN CASES

Pub. L. 101–239, title VI, §6109, Dec. 19, 1989, 103 Stat. 2213, provided that: ‘‘In the case where more than the correct amount may have been paid to a physician or individual under part B of title XVIII of the Social Security Act [part B of this subchapter] with respect to services furnished during the period beginning on July 1, 1965, and ending on March 31, 1966, as a result of a carrier’s establishing statewide fees for certain procedure codes while the carrier was in the process of implementing the national common procedure coding sys-
§ 1395hh. Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subchapter.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.
(e) Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to non-compliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1395z-2(g) of this title) acting within the scope of the contractor’s contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI of this chapter as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f) Report on areas of inconsistency or conflict

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) information from individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.


References in Text

Parts A and B of this subchapter, referred to in subsec. (f)(2)(A), are classified to sections 1395c et seq. and 1395c et seq., respectively, of this title.

Amendments


Subsec. (e)(1)(B), (C). Pub. L. 108–173, §903(b)(1), added subpars. (B) and (C).


1987—Subsec. (a). Pub. L. 100–203, §4035(b), designated existing provisions as par. (1) and added par. (2).

Subsec. (c). Pub. L. 100–203, §4035(e), added subsec. (c).

1986—Pub. L. 99–509 designated existing provisions as subsec. (a) and added subsec. (b).

Effective Date of 2003 Amendment

Pub. L. 108–173, title IX, §902(a)(2), Dec. 8, 2003, 117 Stat. 2375, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003]. The Secretary of Health and Human Services shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.";

Pub. L. 108–173, title IX, §902(b)(2), Dec. 8, 2003, 117 Stat. 2376, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to final regulations published on or after the date of the enactment of this Act [Dec. 8, 2003]."
APPLICATION OF CERTAIN PROVISIONS OF SUBCHAPTER II

The provisions of sections 406 and 416(j) of this title, and of subsections (a), (d), (e), (h), (i), (j), (k), and (l) of section 405 of this title, shall also apply with respect to this subchapter to the same extent as they are applicable with respect to subchapter II of this chapter, except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.


AMENDMENTS

1994—Pub. L. 103–296 inserted before period at end ‘‘…except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively’’.


EFFECTIVE DATE OF 1994 AMENDMENT


EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–603 not applicable to any act, statements, or representations made or committed prior to Oct. 30, 1972, see section 242(d) of Pub. L. 92–603, set out as an Effective Date note under section 1320a–7b of this title.

§ 1395jj. Designation of organization or publication by name

Designation in this subchapter, by name, of any nongovernmental organization or publication shall not be affected by change of name of such organization or publication, and shall apply to any successor organization or publication which the Secretary finds serves the purpose for which such designation is made.


§ 1395kk. Administration of insurance programs (a) Functions of Secretary; performance directly or by contract

Except as otherwise provided in this subchapter and in the Railroad Retirement Act of 1974 (45 U.S.C. 231 et seq.), the insurance programs established by this subchapter shall be administered by the Secretary. The Secretary may perform any of his functions under this subchapter directly, or by contract providing for
payment in advance or by way of reimbursement, and in such installments, as the Secretary may deem necessary.

(b) Contracts to secure special data, actuarial information, etc.

The Secretary may contract with any person, agency, or institution to secure on a reimbursable basis such special data, actuarial information, and other information as may be necessary in the carrying out of his functions under this subchapter.

(c) Oaths and affirmations

In the course of any hearing, investigation, or other proceeding that he is authorized to conduct under this subchapter, the Secretary may administer oaths and affirmations.

(d) Inclusion of Medicare provider and supplier payments in Federal Payment Levy Program

(1) In general

The Centers for Medicare & Medicaid Services shall take all necessary steps to participate in the Federal Payment Levy Program under section 6331(h) of the Internal Revenue Code of 1986 as soon as possible and shall ensure that—

(A) at least 50 percent of all payments under parts A and B are processed through such program beginning within 1 year after July 15, 2008; 1
(B) at least 75 percent of all payments under parts A and B are processed through such program beginning within 2 years after July 15, 2008; and
(C) all payments under parts A and B are processed through such program beginning not later than September 30, 2011.

(2) Assistance

The Financial Management Service and the Internal Revenue Service shall provide assistance to the Centers for Medicare & Medicaid Services to ensure that all payments described in paragraph (1) are included in the Federal Payment Levy Program by the deadlines specified in that subsection.

(e) Availability of Medicare data

(1) In general

Subject to paragraph (4), the Secretary shall make available to qualified entities (as defined in paragraph (2)) data described in paragraph (3) for the evaluation of the performance of providers of services and suppliers.

(2) Qualified entities

For purposes of this subsection, the term “qualified entity” means a public or private entity that—

(A) is qualified (as determined by the Secretary) to use claims data to evaluate the performance of providers of services and suppliers on measures of quality, efficiency, effectiveness, and resource use; and
(B) agrees to meet the requirements described in paragraph (4) and meets such other requirements as the Secretary may specify, such as ensuring security of data.

(3) Data described

The data described in this paragraph are standardized extracts (as determined by the Secretary) of claims data under parts A, B, and D for items and services furnished under such parts for one or more specified geographic areas and time periods requested by a qualified entity. The Secretary shall take such actions as the Secretary deems necessary to protect the identity of individuals entitled to or enrolled for benefits under such parts.

(4) Requirements

(A) Fee

Data described in paragraph (3) shall be made available to a qualified entity under this subsection at a fee equal to the cost of making such data available. Any fee collected pursuant to the preceding sentence shall be deposited into the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title.

(B) Specification of uses and methodologies

A qualified entity requesting data under this subsection shall—

(i) submit to the Secretary a description of the methodologies that such qualified entity will use to evaluate the performance of providers of services and suppliers using such data;
(ii)(I) except as provided in subclause (II), if available, use standard measures, such as measures endorsed by the entity with a contract under section 1395aaa(a) of this title and measures developed pursuant to section 299b–31 of this title; or
(II) use alternative measures if the Secretary, in consultation with appropriate stakeholders, determines that use of such alternative measures would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by such standard measures;
(iii) include data made available under this subsection with claims data from sources other than claims data under this subchapter in the evaluation of performance of providers of services and suppliers;
(iv) only include information on the evaluation of performance of providers and suppliers in reports described in subparagraph (C);
(v) make available to providers of services and suppliers, upon their request, data made available under this subsection; and
(vi) prior to their release, submit to the Secretary the format of reports under subparagraph (C).

(C) Reports

Any report by a qualified entity evaluating the performance of providers of services and suppliers using data made available under this subsection shall—

(i) include an understandable description of the measures, which shall include quality measures and the rationale for use of other measures described in subparagraph (B)(ii)(II), risk adjustment methods, physi-

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1 See References in Text note below.
ian attribution methods, other applicable methods, data specifications and limitations, and the sponsors, so that consumers, providers of services and suppliers, health plans, researchers, and other stakeholders can assess such reports;

(ii) be made available confidentially, to any provider of services or supplier to be identified in such report, prior to the public release of such report, and provide an opportunity to appeal and correct errors;

(iii) only include information on a provider of services or supplier in an aggregate form as determined appropriate by the Secretary; and

(iv) except as described in clause (ii), be made available to the public.

(D) Approval and limitation of uses

The Secretary shall not make data described in paragraph (3) available to a qualified entity unless the qualified entity agrees to release the information on the evaluation of performance of providers of services and suppliers. Such entity shall only use such data, and information derived from such evaluation, for the reports under subparagraph (C). Data released to a qualified entity under this subsection shall not be subject to discovery or admission as evidence in judicial or administrative proceedings without consent of the applicable provider of services or supplier.


Effective Date of 2008 Amendment


Effective Date of 1974 Amendment


Effective Date of 1965 Amendment

Amendment by Pub. L. 89–97 applicable to calendar year 1966 or to any subsequent calendar year but only if by October 1 immediately preceding such calendar year the Railroad Retirement Tax Act provides for a maximum amount of monthly compensation taxable under such Act during all months of such calendar year equal to one-twelfth of maximum wages which Federal Insurance Contributions Act provides may be counted for such calendar year, see section 111(e) of Pub. L. 89–97.

§1395kk–1. Contracts with medicare administrative contractors
(a) Authority

(1) Authority to enter into contracts

The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

(2) Eligibility of entities

An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph (4) only if—

(A) the entity has demonstrated capability to carry out such function;

(B) the entity complies with such conflicts of interest standards as are generally applicable to Federal acquisition and procurement;

(C) the entity has sufficient assets to financially support the performance of such function; and

(D) the entity meets such other requirements as the Secretary may impose.

(3) Medicare administrative contractor defined

For purposes of this subchapter and subchapter XI of this chapter—

(A) In general

The term “medicare administrative contractor” means an agency, organization, or other person with a contract under this section.

(B) Appropriate medicare administrative contractor

With respect to the performance of a particular function in relation to an individual
entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the "appropriate" medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

(4) Functions described

The functions referred to in paragraphs (1) and (2) are payment functions (including the function of developing local coverage determinations, as defined in section 1395ff(f)(2)(B) of this title), provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, as follows:

(A) Determination of payment amounts

Determining (subject to the provisions of section 1395oo of this title and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this subchapter to be made to providers of services, suppliers and individuals.

(B) Making payments

Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making such payments).

(C) Beneficiary education and assistance

Providing education and outreach to individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, and providing assistance to those individuals with specific issues, concerns, or problems.

(D) Provider consultative services

Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this subchapter and otherwise to qualify as providers of services or suppliers.

(E) Communication with providers

Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary.

(F) Provider education and technical assistance

Performing the functions relating to provider education, training, and technical assistance.

(G) Additional functions

Performing such other functions, including (subject to paragraph (5)) functions under the Medicare Integrity Program under section 1395ddd of this title, as are necessary to carry out the purposes of this subchapter.

(5) Relationship to MIP contracts

(A) Nonduplication of duties

In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B of this subchapter do not duplicate activities carried out under a contract entered into under the Medicare Integrity Program under section 1395ddd of this title. The previous sentence shall not apply with respect to the activity described in section 1395ddd(b)(5) of this title (relating to prior authorization of certain items of durable medical equipment under section 1395m(a)(15) of this title).

(B) Construction

An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1395ddd of this title.

(6) Application of Federal Acquisition Regulation

Except to the extent inconsistent with a specific requirement of this section, the Federal Acquisition Regulation applies to contracts under this section.

(b) Contracting requirements

(1) Use of competitive procedures

(A) In general

Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account performance quality as well as price and other factors.

(B) Renewal of contracts

The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 6101 of title 41 or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every 5 years.

(C) Transfer of functions

The Secretary may transfer functions among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact information for the contractors involved).
(D) Incentives for quality

The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

(2) Compliance with requirements

No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

(3) Performance requirements

(A) Development of specific performance requirements

(i) In general

The Secretary shall develop contract performance requirements to carry out the specific requirements applicable under this subchapter to a function described in subsection (a)(4) of this section and shall develop standards for measuring the extent to which a contractor has met such requirements. Such requirements shall include specific performance duties expected of a medical director of a medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor.

(ii) Consultation

In developing such performance requirements and standards for measurement, the Secretary shall consult with providers of services, organizations representative of beneficiaries under this subchapter, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

(iii) Publication of standards

The Secretary shall make such performance requirements and measurement standards available to the public.

(B) Considerations

The Secretary shall include, as one of the standards developed under subparagraph (A), provider and beneficiary satisfaction levels.

(C) Inclusion in contracts

All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements—

(i) shall reflect the performance requirements published under subparagraph (A), but may include additional performance requirements;

(ii) shall be used for evaluating contractor performance under the contract; and

(iii) shall be consistent with the written statement of work provided under the contract.

(4) Information requirements

The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees—

(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this subchapter; and

(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this subchapter.

(5) Surety bond

A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give surety bond to the United States in such amount as the Secretary may deem appropriate.

(e) Terms and conditions

(1) In general

A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection (a)(4)(B) of this section.

(2) Prohibition on mandates for certain data collection

The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this subchapter with data used in the administration of this subchapter for purposes of identifying situations in which the provisions of section 1395y(b) of this title may apply.

(d) Limitation on liability of medicare administrative contractors and certain officers

(1) Certifying officer

No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual’s obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

(2) Disbursing officer

No disbursing officer shall, in the absence of the reckless disregard of the officer’s obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which
meets the applicable requirements for such internal controls established by the Comptroller General of the United States) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) Liability of medicare administrative contractor

(A) In general

No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

(B) Relationship to False Claims Act

Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31.

(4) Indemnification by Secretary

(A) In general

Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating to the claims administration process under this subchapter, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons.

(B) Conditions

The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

(C) Scope of indemnification

Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal expenses).

(D) Written approval for settlements or compromises

A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

(E) Construction

Nothing in this paragraph shall be construed—

(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subparagraph (A); or

(ii) to permit the payment of costs not otherwise allowable, reasonable, or allocable under the Federal Acquisition Regulation.

(e) Requirements for information security

(1) Development of information security program

A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) of this section (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this subchapter. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b) of title 44 (other than the requirements under title 44). A contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) shall undergo an evaluation of the information security of the contractor with respect to such functions under this subchapter. The evaluation shall—

(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor’s information systems (as defined in section 3502(b) of title 44) relating to such functions under this subchapter and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40.

(B) Deadline for initial evaluation

(i) New contractors

In the case of a medicare administrative contractor covered by this subsection that
Incentives to improve contractor performance

The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers. The Secretary shall establish and make known to providers of services and suppliers performance requirements the standards established under subsection (b)(3) of this section. Such standards shall be consistent with the performance requirements established under paragraph (2) and (3); and (ii) monitor the accuracy, consistency, and timeliness of the information so provided. The Secretary shall address the results of such evaluations in response to written and telephone inquiries under this subsection.

Monitoring of contractor responses

(A) In general

Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph (B)—

(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and

(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

(B) Development of standards

(i) In general

The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3) of this section.

(ii) Evaluation

In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

Authorization of appropriations

There are authorized to be appropriated such sums as are necessary to carry out this sub-section.

REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsecs. (a)(3)(B), (4)(3)(A) and (g)(1)(3), (4)(B)(ii), are classified to sections 1395c et seq. and 1395et seq., respectively, of this title.

CODIFICATION


AMENDMENTS

2010—Subsec. (b). Pub. L. 111–152 struck out subsec. (b) which related to conduct of prepayment review.

2003—Subsec. (b)(3)(A)(i). Pub. L. 108–173, § 940A(b), inserted at end “Such requirements shall include specific performance duties expected of a medical director of a Medicare administrative contractor, including requirements relating to professional relations and the availability of such director to conduct medical determination activities within the jurisdiction of such a contractor.”


EFFECTIVE DATE OF 2003 AMENDMENT


“(1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) [amending this section] shall take effect 1 year after the date of the enactment of this Act [Dec. 8, 2003].

“(2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary [of Health and Human Services] shall first issue regulations under section 1874A(h) of the Social Security Act [subsec. (h) of this section], as added by subsection (a), by not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003].

“(3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act [subsec. (b)(1)(B) of this section], as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003]) as the Secretary shall specify.”

EFFECTIVE DATE; TRANSITION RULE


“(1) EFFECTIVE DATE—

“(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section [enacting this section and amending sections 1395h and 1395u of this title] shall take effect on October 1, 2005, and the Secretary [of Health and Human Services] is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

“(B) IN CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act [see Tables for classification], other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

“(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of Medicare administrative contractors for annual contract periods that begin on or after October 1, 2011.

“(2) GENERAL TRANSITION RULES.—

“(A) AUTHORITY TO CONTINUE TO ENTER INTO NEW AGREEMENTS AND CONTRACTS AND WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.—Prior to October 1, 2005, the Secretary may, consistent with subparagraph (B), continue to enter into agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u). The Secretary may enter into new agreements under section 1816 prior to October 1, 2005, without regard to any of the provider nomination provisions of such section.

“(B) APPROPRIATE TRANSITION.—The Secretary shall take such steps as are necessary to provide for an appropriate transition from agreements under section 1816 and contracts under section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A (this section), as added by subsection (a)(1).

“(3) AUTHORIZING CONTINUATION OF MPI FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER TRANSITION CONTRACTS.—Notwithstanding the amendments made by this section [enacting this section and amending sections 1395h and 1395u of this title], the provisions contained in the exception in section 1886(d)(2) of the Social Security Act (42 U.S.C. 1395dd(d)(2)) shall continue to apply during the period that begins on the date of the enactment of this Act [Dec. 8, 2003] and ends on October 1, 2011, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act (this section), as inserted by subsection (a)(1), that continues the activities referred to in such provisions.”

CONSTRUCTION


“(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (commonly known as the ‘False Claims Act’); or

“(2) to prevent or impede the Department of Health and Human Services in any way from its ongoing efforts to eliminate waste, fraud, and abuse in the Medicare program.

“Furthermore, the consolidation of Medicare administrative contracting set forth in this division (Pub. L. 108–173 does not contain any divisions) does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.”

CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS

Pub. L. 108–173, title IX, § 911(a)(2), Dec. 8, 2003, 117 Stat. 2383, provided that: “In developing contract performance requirements under section 1874A(b) of the Social Security Act [subsec. (b) of this section], as inserted by paragraph (1), the Secretary [of Health and Human Services] shall consider inclusion of the performance standards described in sections 1816(i)(2) of such Act [section 1893(h)(2) of this title] (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act.
[section 1395u(b)(2)(B) of this title] (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act [Dec. 8, 2003].

REFERENCES
Pub. L. 108–173, title IX, §911(e), Dec. 8, 2003, 117 Stat. 2386, provided that: “‘On and after the effective date provided under subsection (d)(1) [set out above], any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act [subchapter XI of this chapter and this subchapter] (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor [as provided under section 1874A of the Social Security Act [this section]].’

SECRETARIAL SUBMISSION OF LEGISLATIVE PROPOSAL
Pub. L. 108–173, title IX, §911(f), Dec. 8, 2003, 117 Stat. 2386, provided that: “Not later than 6 months after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this section [enacting this section, amending sections 1395h and 1395u of this title, and enacting provisions set out as notes under this section].’

REPORTS ON IMPLEMENTATION
Pub. L. 108–173, title IX, §911(g), Dec. 8, 2003, 117 Stat. 2386, provided that: “(1) PLAN FOR IMPLEMENTATION.—By not later than October 1, 2004, the Secretary [of Health and Human Services] shall submit a report to Congress and the Comptroller General of the United States that describes the plan for implementation of the amendments made by this section [enacting this section and amending sections 1395h and 1395u of this title]. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

“(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

“(A) The number of contracts that have been competitively bid as of such date.

“(B) The distribution of functions among contracts and contractors.

“(C) A timeline for complete transition to full competition.

“(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.”

APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS
Pub. L. 108–173, title IX, §912(b), Dec. 8, 2003, 117 Stat. 2386, provided that: “(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act [subsection (e)(2) of this section] (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

“(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal intermediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act [Dec. 8, 2003], the first evaluation under section 1874A(e)(2)(A) of the Social Security Act [subsection (e)(2)(A) of this section] (as added by subsection (a), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary [of Health and Human Services]) by not later than 1 year after such date.”

Pub. L. 108–173, title IX, §912(b)(2), Dec. 8, 2003, 117 Stat. 2389, provided that: “The provisions of section 1874A(f) of the Social Security Act [subsection (f) of this section], as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.”

Pub. L. 108–173, title IX, §912(c)(3), Dec. 8, 2003, 117 Stat. 2390, provided that: “The provisions of section 1874A(h) of the Social Security Act [subsection (h) of this section], as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.”

Pub. L. 108–173, title IX, §934(c), Dec. 8, 2003, 117 Stat. 2407, provided that: “The provisions of section 1874A(h) of the Social Security Act [subsection (h) of this section], as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.”

POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOCUMENTATION GUIDELINES
Pub. L. 108–173, title IX, §941, Dec. 8, 2003, 117 Stat. 2418, provided that: “(a) IN GENERAL.—The Secretary [of Health and Human Services] may not implement any new or modified documentation guidelines (which for purposes of this section includes clinical examples) for evaluation and management physician services under the [sic] title XVIII of the Social Security Act [this subchapter] on or after the date of the enactment of this Act [Dec. 8, 2003] unless the Secretary—

“(1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;

“(2) has established a plan that contains specific goals, including a schedule, for improving the use of such guidelines;

“(3) has conducted appropriate and representative pilot projects under subsection (b) to test such guidelines;

“(4) finds, based on reports submitted under subsection (b)(5) with respect to pilot projects conducted for such or related guidelines, that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

“(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

“(b) PILOT PROJECTS TO TEST MODIFIED OR NEW EVALUATION AND MANAGEMENT DOCUMENTATION GUIDELINES.—

“(1) IN GENERAL.—With respect to proposed new or modified documentation guidelines referred to in subsection (a), the Secretary shall conduct under this subsection appropriate and representative pilot projects to test the proposed guidelines.

“(2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

“(A) be voluntary;

“(B) be of sufficient length as determined by the Secretary (but in no case to exceed 1 year) to allow for preparatory physician and medicare contractor
education, analysis, and use and assessment of potential evaluation and management guidelines; and

"(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

"(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this subsection with respect to proposed new or modified documentation guidelines—

"(A) at least one shall focus on a peer review method by physicians (not employed by a Medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to codes used for billing purposes for such services;

"(B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;

"(C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and

"(D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.

"(4) STUDY OF IMPACT.—Each pilot project shall examine the effect of the proposed guidelines on—

"(A) different types of physician practices, including those with fewer than 10 full-time-equivalent employees (including physicians); and

"(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

"(5) REPORT ON PILOT PROJECTS.—Not later than 6 months after the date of completion of pilot projects carried out under this subsection with respect to a proposed guideline described in paragraph (1), the Secretary shall submit to Congress a report on the study conducted under paragraph (1).

"(6) REPORT TO CONGRESS.—

"(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

"(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

"(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

"(1) identify clinically relevant documentation needed to code accurately and assess coding levels accurately;

"(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

"(3) increase accuracy by reviewers; and

"(4) educate both physicians and reviewers.

"(d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN CLAIMS.—

"(1) STUDY.—The Secretary shall carry on a study of the matters described in paragraph (2).

"(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are—

"(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act (this subchapter); and

"(B) consideration of systems other than current coding and documentation requirements for payment for such physician services.

"(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

"(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider require-

ments of administrative simplification under part C of title XI of the Social Security Act [part C of subchapter XI of this chapter].

"(5) REPORT TO CONGRESS.—

"(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

"(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall submit a report on such analysis to Congress.

"(6) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

"(7) DEFINITIONS.—In this section—

"(1) the term 'rural area' has the meaning given that term in section 1866(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D)); and

"(2) the term 'teaching settings' are those settings described in section 415.150 of title 42, Code of Federal Regulations.

§ 1395j. Studies and recommendations

(a) Health care of the aged and disabled

The Secretary shall carry on studies and develop recommendations to be submitted from time to time to the Congress relating to health care of the aged and the disabled, including studies and recommendations concerning (1) the adequacy of existing personnel and facilities for health care for purposes of the programs under parts A and B of this subchapter; (2) methods for encouraging the further development of efficient and economical forms of health care which are a constructive alternative to inpatient hospital care; and (3) the effects of the deductibles and coinsurance provisions upon beneficiaries, persons who provide health services, and the financing of the program.

(b) Operation and administration of insurance programs

The Secretary shall make a continuing study of the operation and administration of this subchapter (including a validation of the accreditation process of national accreditation bodies under section 1395b(a) of this title) the operation and administration of health maintenance organizations authorized by section 226 of the Social Security Amendments of 1972 [42 U.S.C. 1395mm], the experiments and demonstration projects authorized by section 402 of the Social Security Amendments of 1967 [42 U.S.C. 1395b–1] and the experiments and demonstration projects authorized by section 222(a) of the Social Security Amendments of 1972 [42 U.S.C. 1395–1 note]), and shall transmit to the Congress annually a report concerning the operation of such programs.


So in original. Probably should be followed by a comma.

REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsec. (a), are classified to sections 1395cc et seq. and 1396 et seq., respectively, of this title.

Section 226 of the Social Security Amendments of 1972, referred to in subsec. (b), is section 226 of Pub. L. 92–603, which enacted section 1395mm of this title and provisions set out as notes under that section and amended this section and sections 1395f, 1395f, and 1396 of this title.

Section 402 of the Social Security Amendments of 1967, referred to in subsec. (b), is section 402 of Pub. L. 90–248, which enacted section 1395b–1 of this title and amended this section.

Section 222(a) of the Social Security Amendments of 1972, referred to in subsec. (b), is section 222(a) of Pub. L. 92–603, which enacted provisions set out as note under section 1395b–1 of this title.

AMENDMENTS

2008—Subsec. (b). Pub. L. 110–275 substituted “national accreditation bodies under section 1395b–6(a) of this title” for “the Joint Commission on Accreditation of Hospitals”.

2003—Subsec. (b). Pub. L. 108–173 substituted “this subchapter” for “the insurance programs under parts A and B of this subchapter”.


1988—Subsec. (c)(3). Pub. L. 100–647 amended par. (3) generally. Prior to amendment, par. (3) read as follows: “For purposes of carrying out the research program, there are authorized to be appropriated—

“(A) from the Federal Hospital Insurance Trust Fund $4,000,000 for fiscal year 1987 and $5,000,000 for each fiscal year 1988 and 1989, and

“(B) from the Federal Supplementary Medical Insurance Trust Fund $2,000,000 for fiscal year 1987 and $2,500,000 for each of fiscal years 1988 and 1989.”


1984—Subsec. (b). Pub. L. 98–369 struck out “the” after “Joint Commission on”.


Subsec. (b). Pub. L. 92–603, §§ 222(c), 226(d)(1), 244(d), substituted “(including the experimentation authorized by section 402 of the Social Security Amendments of 1967)” for “(including the experimentation authorized by section 402 of the Social Security Amendments of 1972)”.

1968—Subsec. (b). Pub. L. 90–248 inserted “(including the experimentation authorized by section 402 of the Social Security Amendments of 1967)” after “under parts A and B of this subchapter”.

Effective Date of 2008 Amendment; Transition Rules

Amendment by Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(d) of Pub. L. 110–275, set out as a note under section 1395bb of this title.

Effective Date of 1989 Amendment

Section 6103(b)(3)(A) of Pub. L. 101–239 provided that the amendment made by that section is effective for fiscal years beginning after fiscal year 1990.

Effective Date of 1984 Amendment

Amendment by 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 254(e)(1) of Pub. L. 98–369, set out as a note under section 1395aa–1 of this title.

Effective Date of 1972 Amendment

Amendment by section 226(d) of Pub. L. 92–603 effective with respect to services provided on or after July 1, 1973, see section 226(f) of Pub. L. 92–603, set out as an Effective Date note under section 1395mm of this title.

INSTITUTE OF MEDICINE EVALUATION AND REPORT ON HEALTH CARE PERFORMANCE MEASURES


“(a) EVALUATION.—

“(1) IN GENERAL.—Not later than the date that is 2 months after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences (in this section referred to as the ‘Institute’) shall conduct an evaluation of leading health care performance measures in the public and private sectors and options to implement policies that align performance with payment under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

“(2) SPECIFIC MATTERS EVALUATED.—In conducting the evaluation under paragraph (1), the Institute shall:

“(A) catalogue, review, and evaluate the validity of leading health care performance measures;

“(B) catalogue and evaluate the success and utility of alternative performance incentive programs in public or private sector settings; and

“(C) identify and prioritize options to implement policies that align performance with payment under the medicare program that indicate—

“(i) the performance measurement set to be used and how that measurement set will be updated;

“(ii) the payment policy that will reward performance; and

“(iii) the key implementation issues (such as data and information technology requirements) that must be addressed.

“(3) SCOPE OF HEALTH CARE PERFORMANCE MEASURES.—The health care performance measures described in paragraph (2)(A) shall encompass a variety of perspectives, including physicians, hospitals, other health care providers, health plans, purchasers, and patients.

“(4) CONSULTATION WITH MEDPAC.—In evaluating the matters described in paragraph (2)(C), the Institute shall consult with the Medicare Payment Advisory Commission established under section 1805 of the Social Security Act (42 U.S.C. 1395b–6).”
“(b) REPORT.—Not later than the date that is 18 months after the date of enactment of this Act [Dec. 8, 2003], the Institute shall submit to the Secretary and appropriate committees of the Senate and House of Representatives a report on the evaluation conducted under subsection (a)(1) describing the findings of such evaluation and recommendations for an overall strategy and approach for aligning payment with performance, including options for updating performance measures, in the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act [parts A and B of this subchapter], the Medicare Advantage program under part C of such title [part C of this subchapter], and any other programs under such title XVIII [this subchapter].

“(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for purposes of conducting the evaluation and preparing the report required by this section.”

GAO STUDY ON ACCESS TO PHYSICIANS’ SERVICES

Pub. L. 108–175, title VI, §604, Dec. 8, 2003, 117 Stat. 2901, provided that:

“(a) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians’ services under the medicare program. The study shall include—

“(1) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program [part B of this subchapter];

“(2) an examination of changes in the use by beneficiaries of physicians’ services over time; and

“(3) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

“(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003], the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include a determination whether—

“(1) data from claims submitted by physicians under part B of the medicare program [part B of this subchapter] indicate potential access problems for medicare beneficiaries in certain geographic areas; and

“(2) access by medicare beneficiaries to physicians’ services may have improved, remained constant, or deteriorated over time.

STUDY ON ENROLLMENT PROCEDURES FOR GROUPS THAT RETAIN INDEPENDENT CONTRACTOR PHYSICIANS

Pub. L. 106–554, §1(a)(6) [title IV, §437], Dec. 21, 2000, 114 Stat. 2783, 2783A–527, provided that:

“(a) STUDY.—The Comptroller General of the United States shall conduct a study on the post-payment audit process under the medicare program under title XVIII of the Social Security Act [this subchapter] as such process applies to physicians, including the proper level of resources that the Health Care Financing Administration should devote to educating physicians regarding—

“(A) coding and billing;

“(B) documentation requirements; and

“(C) the calculation of overpayments.

“(2) REPORT.—Not later than 18 months 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 paragraph (1) together with specific recommendations for changes or improvements in the post-payment audit process described in such paragraph.

“(b) GAO STUDY ON ADMINISTRATION AND OVERSIGHT.—

“(1) STUDY.—The Comptroller General of the United States shall conduct a study on the aggregate effects of regulatory, audit, oversight, and paperwork burdens on physicians and other health care providers participating in the medicare program under title XVIII of the Social Security Act [this subchapter].

“(2) REPORT.—Not later than 18 months 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 paragraph (1) together with recommendations regarding any area in which—

“(A) a reduction in paperwork, an ease of administration, or an appropriate change in oversight and review may be accomplished; or

“(B) additional payments or education are needed to assist physicians and other health care providers in understanding and complying with any legal or regulatory requirements.

STUDY AND REPORT REGARDING UTILIZATION OF PHYSICIANS’ SERVICES BY MEDICARE BENEFICIARIES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §211(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–349, provided that:

“(1) STUDY BY SECRETARY.—The Secretary of Health and Human Services, acting through the Administrator of the Agency for Health Care Policy and Research, shall conduct a study of the issues specified in paragraph (2).

“(2) ISSUES TO BE STUDIED.—The issues specified in this paragraph are the following:

“(A) The various methods for accurately estimating the economic impact on expenditures for physicians’ services under the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) [parts A and B of this subchapter] resulting from—

“(i) improvements in medical capabilities;

“(ii) advancements in scientific technology;

“(iii) demographic changes in the types of medicare beneficiaries that receive benefits under such program; and

“(iv) geographic changes in locations where medicare beneficiaries receive benefits under such program.

“(B) The rate of usage of physicians’ services under the original medicare fee-for-service program under parts A and B of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) among beneficiaries between ages 65 and 74, 75 and 84, 85 and over, and disabled beneficiaries under age 65.

“(C) Other factors that may be reliable predictors of beneficiary utilization of physicians’ services under the original medicare fee-for-service program

GAO STUDIES AND REPORTS ON MEDICARE PAYMENTS

Pub. L. 106–554, §1(a)(6) [title IV, §437], Dec. 21, 2000, 114 Stat. 2783, 2783A–527, provided that:

“(a) GAO STUDY ON HCFA POST-PAYMENT AUDIT PROCESS.—

“(1) STUDY.—The Comptroller General of the United States shall conduct a study on the post-payment audit process under the medicare program under title XVIII of the Social Security Act [this subchapter] as such process applies to physicians, including the proper level of resources that the Health Care Financing Administration should devote to educating physicians regarding—

“(A) coding and billing;

“(B) documentation requirements; and

“(C) the calculation of overpayments.

“(2) REPORT.—Not later than 18 months 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 paragraph (1) together with specific recommendations for changes or improvements in the post-payment audit process described in such paragraph.

“§1395I/
under parts A and B of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.).

"(3) REPORT TO CONGRESS.—Not later than 3 years after the date of the enactment of this Act [Nov. 29, 1999], the Secretary of Health and Human Services shall submit a report to Congress setting forth the results of the study conducted pursuant to paragraph (1), together with any recommendations the Secretary determines are appropriate.

"(4) MEDDAC REPORT TO CONGRESS.—Not later than 180 days after the date of submission of the report under paragraph (3), the Medicare Payment Advisory Commission shall submit a report to Congress that includes—

"(A) an analysis and evaluation of the report submitted under paragraph (3); and

"(B) such recommendations as it determines are appropriate."

STUDY OF ADULT DAY CARE SERVICES

STUDY TO DEVELOP A STRATEGY FOR QUALITY REVIEW AND ASSURANCE
Section 1391(d) of Pub. L. 99–509, as amended by Pub. L. 100–203, title IV, § 406(2)(A), Apr. 7, 1987, 101 Stat. 135–133, directed Secretary of Health and Human Services to arrange, with the National Academy of Sciences or other appropriate nonprofit private entity, for a study to design a strategy for reviewing and assuring the quality of care for which payment may be made under this subchapter, specified items to be included in the study, and directed Secretary to submit to Congress, not later than Jan. 1, 1990, a report on the study with recommendations with respect to strengthening quality assurances and review activities for services furnished under the medicare program.

ESPECIAL TREATMENT OF STATES FORMERLY UNDER WAIVER
For treatment of hospitals in States which have had a waiver approved under this section, upon termination of waiver, see section 1395w(b) of this title.

DRUG DETOXIFICATION MEDICARE COVERAGE AND FACILITY INCENTIVES

LEGISLATIVE RECOMMENDATIONS REGARDING REIMBURSEMENT FOR OPTOMETRISTS’ SERVICES
Pub. L. 96–499, title IX, § 937(b), Dec. 5, 1980, 94 Stat. 2640, provided that the Secretary of Health and Human Services submit to the Congress by Jan. 1, 1982, legislative recommendations with respect to reimbursement under title XVIII of the Social Security Act [this subchapter] for services furnished by optometrists in connection with cataracts and such other services which they are legally authorized to perform.

DEMONSTRATION PROJECTS, STUDIES, AND REPORTS: NUTRITIONAL THERAPY, SECOND OPINION COST-SHARING, SERVICES OF REGISTERED DIETITIANS, SERVICES OF CLINICAL SOCIAL WORKERS, ORTHOPEDIC SHOE FITTING, RESPIRATORY THERAPY SERVICES, AND FOOT CONDITIONS; GRANTS, PAYMENTS, AND EXPENDITURES
Pub. L. 96–499, title IX, § 958A, Dec. 5, 1980, 94 Stat. 2648, directed Secretary of Health and Human Services to carry out certain demonstration projects and conduct certain studies as follows: (a) a demonstration project to determine extent to which nutritional therapy in early renal failure could ward off the disease with resultant substantive deferment of dialysis, and aspects of making such therapy available under this subchapter, report to Congress to be submitted within twenty-four months of Dec. 5, 1980; (b) demonstration projects with respect to waiving the applicable cost sharing amounts which beneficiaries under this subchapter had to pay for obtaining a second opinion on having surgery, report to be submitted within one year after Dec. 5, 1980; (c) a study of conditions under which services of registered dietitians could be covered as a home health benefit under this subchapter, report to be submitted within twenty-four months of Dec. 5, 1980; (d) demonstration projects to determine aspects of making services of clinical social workers more generally available under this subchapter, report to be submitted within twenty-four months of Dec. 5, 1980; (e) a study of methods for providing coverage under part B of this subchapter for orthopedic shoes for individuals with disabling or deforming conditions requiring special fitting considerations, or requiring special shoes in conjunction with the use of an orthosis or foot support, report to be submitted no later than July 1, 1981; (f) a study of conditions under which services with respect to respiratory therapy could be covered and a home health benefit under this subchapter, report to be submitted within twenty-four months of Dec. 5, 1980; and (g) a study analyzing cost effects of alternative approaches to improving coverage under this subchapter for treatment of various types of foot conditions, report to be submitted within twenty-four months of Dec. 5, 1980. Payments and expenditures for such studies and projects were to be made in appropriate part from the Federal Hospital Insurance Trust Fund established by section 1395i of this title, and the Federal Supplementary Medical Insurance Trust Fund established by section 1395k of this title.

DEMONSTRATION PROJECT RELATING TO THE TERMINALLY ILL
Pub. L. 96–265, title V, § 506, June 9, 1980, 94 Stat. 475, authorized Secretary of Health and Human Services to provide for participation, by Social Security Administration, in a demonstration project relating to the terminally ill then being conducted within the Department of Health and Human Services, the purpose of such participation to be to study impact on terminally ill of provisions of disability programs administered by Social Security Administration and to determine what is best to provide services needed by persons who were terminally ill through programs over which the Social Security Administration had administrative responsibility, and authorized to be appropriated necessary sums not in excess of $2,000,000 for any fiscal year.

REPORT TO CONGRESS WITH RESPECT TO URBAN OR RURAL COMPREHENSIVE MENTAL HEALTH CENTERS AND CENTERS FOR TREATMENT OF ALCOHOLISM AND DRUG ABUSE; SUBMISSION NO LATER THAN JUNE 13, 1978

STUDY AND REVIEW BY COMPTROLLER GENERAL OF ADMINISTRATIVE STRUCTURE FOR PROCESSING MEDICARE CLAIMS; REPORT TO CONGRESS
Pub. L. 95–142, § 12, Oct. 25, 1977, 91 Stat. 1197, directed Comptroller General to conduct a comprehensive study and review of administrative structure established for processing of claims under this subchapter for purpose of determining whether and to what extent more effi-
cient claims administration under this subchapter could be achieved and directed Comptroller General to submit to Congress no later than July 1, 1979, a complete report with respect to such study and review.

Report by Secretary of Health, Education, and Welfare on delivery of home health and other in-home services: contents; consultation requirements; submission to Congress

Pub. L. 95-142, §18, Oct. 25, 1977, 91 Stat. 1202, directed Secretary of Health, Education, and Welfare, not later than the same year after Oct. 25, 1977, to submit to appropriate committees of Congress a report analyzing, evaluating, and making recommendations with respect to all aspects of delivery of home health and other in-home services authorized to be provided under subchapters XVIII, XIX, and XX of this chapter.

§ 1395mm. Payments to health maintenance organizations and competitive medical plans

(a) Rates and adjustments

(1)(A) The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) not later than September 7 before the calendar year concerned—

(i) a per capita rate of payment for each class of individuals who are enrolled under this section with an eligible organization which has entered into a risk-sharing contract and who are entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, and

(ii) a per capita rate of payment for each class of individuals who are so enrolled with such an organization and who are enrolled under part B of this subchapter only.

For purposes of this section, the term “risk-sharing contract” means a contract entered into under subsection (g) of this section and the term “reasonable cost reimbursement contract” means a contract entered into under subsection (h) of this section.

(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence. The Secretary may make retroactive adjustments under clause (i) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with an eligible organization (which has a risk-sharing contract under this section) under a health benefit plan operated, sponsored, or contributed to by the individual’s employer or former employer (or the employer or former employer of the individual’s spouse) and ending on the date on which the individual is enrolled in the plan under this section, except that for purposes of making such retroactive adjustments under this clause, such period may not exceed 90 days.

(II) No adjustment may be made under subclause (I) with respect to any individual who does not certify that the organization provided the individual with the explanation described in subsection (c)(3)(E) of this section at the time the individual enrolled with the organization.

(F)(i) At least 45 days before making the announcement under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall provide for notice to eligible organizations of proposed changes to be made in the methodology or benefit coverage assumptions from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(ii) In each announcement made under subparagraph (A) for a year (beginning with the announcement for 1991), the Secretary shall include an explanation of the assumptions (including any benefit coverage assumptions) and changes in methodology used in the announcement in sufficient detail so that eligible organizations can compute per capita rates of payment for classes of individuals located in each county (or equivalent area) which is in whole or in part within the service area of such an organization.

(2) With respect to any eligible organization which has entered into a reasonable cost reimbursement contract, payments shall be made to such plan in accordance with subsection (h)(2) of this section rather than paragraph (1).

(3) Subject to subsections (c)(2)(B)(ii) and (c)(7) of this section, payments under a contract to an eligible organization under paragraph (1) or (2) shall be instead of the amounts which (in the absence of the contract) would be otherwise payable, pursuant to sections 1395f(b) and 1395a(a) of this title, for services furnished by or through the organization to individuals enrolled with the organization under this section.

(4) For purposes of this section, the term “adjusted average per capita cost” means the average per capita amount that the Secretary estimates in advance (on the basis of actual experience, or retrospective actuarial equivalent based upon an adequate sample and other information and data, in a geographic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for services covered under parts A and B of this subchapter, or part B only, and types of expenses otherwise reimbursable under parts A and B of this subchapter, or part B only (including administrative costs incurred by organizations described in sections 1395h and 1395a of this title), if the services were to be furnished by
other than an eligible organization or, in the case of services covered only under section 1395x(s)(2)(H) of this title, if the services were to be furnished by a physician or as an incident to a physician’s service.

(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The portion of that payment to the organization for a month to be paid by each trust fund shall be determined as follows:

(A) In regard to expenditures by eligible organizations having risk-sharing contracts, the allocation shall be determined each year by the Secretary based on the relative weight that benefits from each fund contribute to the adjusted average per capita cost.

(B) In regard to expenditures by eligible organizations operating under a reasonable cost reimbursement contract, the initial allocation shall be based on the plan’s most recent budget, such allocation to be adjusted, as needed, after cost settlement to reflect the distribution of actual expenditures.

The remainder of that payment shall be paid by the former trust fund.

(6) Subject to subsections (c)(2)(B)(ii) and (c)(7) of this section, if an individual is enrolled under this section with an eligible organization having a risk-sharing contract, only the eligible organization shall be entitled to receive payments from the Secretary under this subchapter for services furnished to the individual.

(b) Definitions; requirements

For purposes of this section, the term “eligible organization” means a public or private entity (which may be a health maintenance organization or a competitive medical plan), organized under the laws of any State, which—

(1) is a qualified health maintenance organization (as defined in section 300e–9(d) of this title), or

(2) meets the following requirements:

(A) The entity provides to enrolled members at least the following health care services:

(i) Physicians’ services performed by physicians (as defined in section 1395x(r)(1) of this title).

(ii) Inpatient hospital services.

(iii) Laboratory, X-ray, emergency, and preventive services.

(iv) Out-of-area coverage.

(B) The entity is compensated (except for deductibles, coinsurance, and copayments) for the provision of health care services to enrolled members by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health care service actually provided to a member.

(C) The entity provides physicians’ services primarily (i) directly through physicians who are either employees or partners of such organization, or (ii) through contracts with individual physicians or one or more groups of physicians (organized on a group practice or individual practice basis).

(D) The entity assumes full financial risk on a prospective basis for the provision of the health care services listed in subparagraph (A), except that such entity may—

(i) obtain insurance or make other arrangements for the cost of providing to any enrolled member health care services listed in subparagraph (A) the aggregate value of which exceeds $5,000 in any year,

(ii) obtain insurance or make other arrangements for the cost of health care service listed in subparagraph (A) provided to its enrolled members other than through the entity because medical necessity required their provision before they could be secured through the entity,

(iii) obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceeded 115 percent of its income for such fiscal year, and

(iv) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(E) The entity has made adequate provision against the risk of insolvency, which provision is satisfactory to the Secretary.

Paragraph (2)(A)(ii) shall not apply to an entity which had contracted with a single State agency administering a State plan approved under subchapter XIX of this chapter for the provision of services (other than inpatient hospital services) to individuals eligible for such services under such State plan on a prepaid risk basis prior to 1970.

(c) Enrollment in plan; duties of organization to enrollees

(1) The Secretary may not enter into a contract under this section with an eligible organization unless it meets the requirements of this subsection and subsection (e) of this section with respect to members enrolled under this section.

(2) (A) The organization must provide to members enrolled under this section, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI of this chapter—

(i) only those services covered under parts A and B of this subchapter, for those members entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, or

(ii) only those services covered under part B of this subchapter, for those members enrolled only under such part, which are available to individuals residing in the geographic area served by the organization,
organizations with risk-sharing contracts under this section and enrolling individuals residing in that part of the service area are required to have an open enrollment period for individuals residing in the part of the service area who were enrolled under the contract as of the date of notice of such discontinued coverage.

(II) The open enrollment periods required under subclause (I) shall be for 30 days and shall begin 30 days after the date that the Secretary provides notice of such requirement.

(III) Enrollment under this clause shall be effective 30 days after the end of the open enrollment period, or, if the Secretary determines that such date is not feasible, such other date as the Secretary specifies.

(B) An individual may enroll under this section with an eligible organization in such manner as may be prescribed in regulations and may terminate his enrollment with the eligible organization as of the beginning of the first calendar month following the date on which the request is made for such termination (or, in the case of financial insolvency of the organization, as may be prescribed by regulations) or, in the case of such an organization with a reasonable cost reimbursement contract, as may be prescribed by regulations. In the case of an individual’s termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this subchapter other than through the organization.

(C) The Secretary may prescribe the procedures and conditions under which an eligible organization that has entered into a contract with the Secretary under this subsection may inform individuals eligible to enroll under this section with the organization about the organization, or may enroll such individuals with the organization. No brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless (i) at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and (ii) the Secretary has not disapproved the distribution of the material. The Secretary shall review all such material submitted and shall disapprove such material if the Secretary determines, in the Secretary’s discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(D) The organization must provide assurances to the Secretary that it will not expel or refuse to re-enroll any such individual because of the individual’s health status or requirements for health care services, and that it will notify each such individual of such fact at the time of the individual’s enrollment.

(E) Each eligible organization shall provide each enrollee, at the time of enrollment and not less frequently than annually thereafter, an explanation of the enrollee’s rights under this section, including an explanation of—
(i) the enrollee’s rights to benefits from the organization,
(ii) the restrictions on payments under this subchapter for services furnished other than by or through the organization,
(iii) out-of-area coverage provided by the organization,
(iv) the organization’s coverage of emergency services and urgently needed care, and
(v) appeal rights of enrollees.

(F) Each eligible organization that provides items and services pursuant to a contract under this section shall provide assurances to the Secretary that in the event the organization ceases to provide such items and services, the organization shall provide or arrange for supplemental coverage of benefits under this subchapter relating to a pre-existing condition with respect to any exclusion period, to all individuals enrolled with the entity who receive benefits under this subchapter, for the lesser of six months or the duration of such period.

(G)(i) Each eligible organization having a risk-sharing contract under this section shall notify individuals eligible to enroll with the organization under this section and individuals enrolled with the organization under this section that—
(I) the organization is authorized by law to terminate or refuse to renew the contract, and
(ii) termination or nonrenewal of the contract may result in termination of the enrollments of individuals enrolled with the organization under this section.

(ii) The notice required by clause (i) shall be included in—
(I) any marketing materials described in subparagraph (C) that are distributed by an eligible organization to individuals eligible to enroll under this section with the organization, and
(II) any explanation provided to enrollees by the organization pursuant to subparagraph (E).

(4) The organization must—
(A) make the services described in paragraph (2) and such other health care services as such individuals have contracted for (i) available and accessible to each such individual, within the area served by the organization, with reasonable promptness and in a manner which assures continuity, and (ii) when medically necessary, available and accessible twenty-four hours a day and seven days a week, and
(B) provide for reimbursement with respect to services which are described in subparagraph (A) and which are provided to such an individual other than through the organization, if (i) the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition and (ii) it was not reasonable given the circumstances to obtain the services through the organization.

(5)(A) The organization must provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the organization provides health care services) and members enrolled with the organization under this section.

(B) A member enrolled with an eligible organization under this section who is dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay is entitled, if the amount in controversy is $100 or more, to a hearing before the Secretary to the same extent as is provided in section 405(b) of this title, and in any such hearing the Secretary shall make the eligible organization a party. If the amount in controversy is $1,000 or more, the individual or eligible organization shall, upon notifying the other party, be entitled to judicial review of the Secretary’s final decision as provided in section 405(g) of this title, and both the individual and the eligible organization shall be entitled to be parties to that judicial review. In applying sections 405(b) and 405(g) of this title as provided in this subparagraph, and in applying section 405(l) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively. The provisions of section 1395ff(b)(1)(E)(ii) of this title shall apply with respect to dollar amounts specified in the first 2 sentences of this subparagraph in the same manner as they apply to the dollar amounts specified in section 1395ff(b)(1)(E)(i) of this title.

(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals, which program (A) stresses health outcomes and (B) provides review by physicians and other health care professionals of the process followed in the provision of such health care services.

(7) A risk-sharing contract under this section shall provide that in the case of an individual who is receiving inpatient hospital services from a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) as of the effective date of the individual’s—
(A) enrollment with an eligible organization under this section—
(i) payment for such services until the date of the individual’s discharge shall be made under this subchapter as if the individual were not enrolled with the organization,
(ii) the organization shall not be financially responsible for payment for such services until the date after the date of the individual’s discharge, and
(iii) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this section; or
(B) termination of enrollment with an eligible organization under this section—
(i) the organization shall be financially responsible for payment for such services after such date and until the date of the individual’s discharge,
(ii) payment for such services during the stay shall not be made under section 1395ww(d) of this title, and
(iii) the organization shall not receive any payment with respect to the individual under this section during the period the individual is not enrolled.
(8) A contract under this section shall provide that the eligible organization shall meet the requirement of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(d) Right to enroll with contracting organization in geographic area

Subject to the provisions of subsection (c)(3) of this section, every individual entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter or enrolled under part B of this subchapter only (other than an individual medically determined to have end-stage renal disease) shall be eligible to enroll under this section with any eligible organization with which the Secretary has entered into a contract under this section and which serves the geographic area in which the individual resides.

(e) Limitation on charges; election of coverage; "adjusted community rate" defined; workmen's compensation and insurance benefits

(1) In no case may—

(A) the portion of an eligible organization's premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under parts A and B of this subchapter) to individuals who are enrolled under this section with the organization and who are entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, or

(B) the portion of its premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to services covered under part B of this subchapter) to individuals who are enrolled under this section with the organization and enrolled under part B of this subchapter only

exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled under this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area, in the State, or in the United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, or enrolled under part B only, respectively, if they were not members of an eligible organization.

(2) If the eligible organization provides to its members enrolled under this section services in addition to services covered under parts A and B of this subchapter, election of coverage for such additional services (unless such services have been approved by the Secretary under sub-section (c)(2) of this section) shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of—

(A) the portion of such organization's premium rate charged, with respect to such additional services, to members enrolled under this section, and

(B) the actuarial value of its deductibles, coinsurance, and copayments charged, with respect to such services to such members exceed the adjusted community rate for such services.

(3) For purposes of this section, the term "adjusted community rate" for a service or services means, at the election of an eligible organization, either—

(A) the rate of payment for that service or services which the Secretary annually determines would apply to a member enrolled under this section with an eligible organization if the rate of payment were determined under a "community rating system" (as defined in section 300e–1(8) of this title, other than subparagraph (C)), or

(B) such portion of the weighted aggregate premium, which the Secretary annually estimates would apply to a member enrolled under this section with the eligible organization, as the Secretary annually estimates is attributable to that service or services, but adjusted for differences between the utilization characteristics of the members enrolled with the eligible organization under this section and the utilization characteristics of the other members of the organization (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of members in other eligible organizations, or individuals in the area, in the State, or in the United States, eligible to enroll under this section with an eligible organization and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Notwithstanding any other provision of law, the eligible organization may (in the case of the provision of services to a member enrolled under this section for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or plan of the United States or a State, under an automobile or liability insurance policy or plan, including a self-insured plan, or under no fault insurance) charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law or policy—

(A) the insurance carrier, employer, or other entity which under such law, plan, or policy is to pay for the provision of such services, or

(B) such member to the extent that the member has been paid under such law, plan, or policy for such services.

(f) Membership requirements

(1) For contract periods beginning before January 1, 1999, each eligible organization with which the Secretary enters into a contract under this section shall have, for the duration of such contract, an enrolled membership at least one-half of which consists of individuals who are not entitled to benefits under this subchapter.

(2) Subject to paragraph (4), the Secretary may modify or waive the requirement imposed by paragraph (1) only—

(A) to the extent that more than 50 percent of the population of the area served by the or-
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ganization consists of individuals who are ent-
titled to benefits under this subchapter or
under a State plan approved under subchapter
XIX of this chapter, or
(4) Effective for contract periods beginning
after December 31, 1996, the Secretary may
determine such an average per capita rate
of payment to be made under subsection (a)(1) of
this section at the beginning of a contract pe-
riod, the Secretary may determine such an aver-
age based on the enrollment experience of other
contractors entered into under this section.
(3) The additional benefits referred to in para-
graph (2) are—
(A) the reduction of the premium rate or
other charges made with respect to services
furnished by the organization to members en-
rolled under this section, or
(B) the provision of additional health bene-
fits,
or both.
(4) Repealed. Pub. L. 100–203, title IV, § 4012(b),
(5) An organization having a risk-sharing con-
tact under this section may (with the approval
of the Secretary) provide that a part of the value
of additional benefits otherwise required to be
provided by reason of paragraph (2) be
withheld and reserved in the Federal Hospital
Insurance Trust Fund and in the Federal Sup-
plementary Medical Insurance Trust Fund (in
such proportions as the Secretary determines to
be appropriate) by the Secretary for subsequent
annual contract periods, to the extent required
to stabilize and prevent undue fluctuations in
the additional benefits offered in those subse-
quent periods by the organization in accordance
with paragraph (3). Any of such value of addi-
tional benefits which is not provided to mem-
ers of the organization in accordance with
paragraph (3) prior to the end of such period,
shall revert for the use of such trust funds.
(6)(A) A risk-sharing contract under this sec-
tion shall require the eligible organization to
provide prompt payment (consistent with the
provisions of sections 1395h(c)(2) and 1395u(c)(2)
of this title) of claims submitted for services
and supplies furnished to individuals pursuant
to such contract, if the services or supplies are
not furnished under a contract between the or-
ganization and the provider or supplier.
(B) In the case of an eligible organization
which the Secretary determines, after notice
and opportunity for a hearing, has failed to
make payments of amounts in compliance with
subparagraph (A), the Secretary may provide for
direct payment of the amounts owed to provid-
ers and suppliers for such covered services fur-
nished to individuals enrolled under this section
under the contract. If the Secretary provides for
the additional benefits described in paragraph
(3) which are selected by the eligible organiza-
tion and which the Secretary finds are at least
equal in value to the difference between that av-
erage per capita payment and the adjusted com-
munity rate (as so reduced) and except that this
paragraph shall not apply with respect to any
organization which elects to receive a lesser
payment to the extent that there is no longer a
difference between the average per capita pay-
ment and adjusted community rate (as so re-
duced) and except that an organization (with the
approval of the Secretary) may provide that a
part of the value of such additional benefits be
withheld and reserved by the Secretary as pro-
vided in paragraph (5). If the Secretary finds
that there is insufficient enrollment experience
to determine an average of the per capita rates
of payment to be made under subsection (a)(1) of
this section at the beginning of a contract pe-
riod, the Secretary may determine such an aver-
age based on the enrollment experience of other
contracts entered into under this section.
(3) The additional benefits referred to in para-
graph (2) are—
(A) the reduction of the premium rate or
other charges made with respect to services
furnished by the organization to members en-
rolled under this section, or
(B) the provision of additional health bene-
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or both.
(4) Repealed. Pub. L. 100–203, title IV, § 4012(b),
(5) An organization having a risk-sharing con-
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erage per capita payment and the adjusted com-
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payment to the extent that there is no longer a
difference between the average per capita pay-
ment and adjusted community rate (as so re-
duced) and except that an organization (with the
approval of the Secretary) may provide that a
part of the value of such additional benefits be
withheld and reserved by the Secretary as pro-
vided in paragraph (5). If the Secretary finds
that there is insufficient enrollment experience
to determine an average of the per capita rates
of payment to be made under subsection (a)(1) of
this section at the beginning of a contract pe-
riod, the Secretary may determine such an aver-
age based on the enrollment experience of other
contracts entered into under this section.
(3) The additional benefits referred to in para-
graph (2) are—
(A) the reduction of the premium rate or
other charges made with respect to services
furnished by the organization to members en-
rolled under this section, or
(B) the provision of additional health bene-
fits,
such direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this section to reflect the amount of the Secretary’s payments (and costs incurred by the Secretary in making such payments).

(h) Reasonable cost reimbursement contract; requirements

(1) If—

(A) the Secretary is not satisfied that an eligible organization has the capacity to bear the risk of potential losses under a risk-sharing contract under this section, or

(B) the eligible organization so elects or has an insufficient number of members to be eligible to enter into a risk-sharing contract under subsection (g)(1) of this section, the Secretary may, if he is otherwise satisfied that the eligible organization is able to perform its contractual obligations effectively and efficiently, enter into a contract with such organization pursuant to which such organization is reimbursed on the basis of its reasonable cost (as defined in section 1395x(v) of this title) in the manner prescribed in paragraph (3).

(2) A reasonable cost reimbursement contract under this subsection may, at the option of such organization, provide that the Secretary—

(A) will reimburse hospitals and skilled nursing facilities either for the reasonable cost (as determined under section 1395x(v) of this title) or for payment amounts determined in accordance with section 1395ww of this title, as applicable, of services furnished to individuals enrolled with such organization pursuant to subsection (d) of this section, and

(B) will deduct the amount of such reimbursement from payment which would otherwise be made to such organization.

If such an eligible organization pays a hospital or skilled nursing facility directly, the amount paid shall not exceed the reasonable cost of the services (as determined under section 1395x(v) of this title) or the amount determined under section 1395ww of this title, as applicable, unless such organization demonstrates to the satisfaction of the Secretary that such excess payments are justified on the basis of advantages gained by the organization.

(3) Payments made to an organization with a reasonable cost reimbursement contract shall be subject to appropriate retroactive corrective adjustment at the end of each contract year so as to assure that such organization is paid for the reasonable cost actually incurred (excluding any part of incurred cost found to be unnecessary in the efficient delivery of health services) or the amounts otherwise determined under section 1395ww of this title for the types of expenses otherwise reimbursable under this subchapter for providing services covered under this subchapter to individuals described in subsection (a)(1) of this section.

(4) Any reasonable cost reimbursement contract with an eligible organization under this subsection shall provide that the Secretary shall require, at such time following the expiration of each accounting period of the eligible organization (and in such form and in such detail) as he may prescribe—

(A) that the organization report to him in an independently certified financial statement its per capita incurred cost based on the types of components of expenses otherwise reimbursable under this subchapter for providing services described in subsection (a)(1) of this section, including therein, in accordance with accounting procedures prescribed by the Secretary, its methods of allocating costs between individuals enrolled under this section and other individuals enrolled with such organization;

(B) that failure to report such information as may be required may be deemed to constitute evidence of likely overpayment on the basis of which appropriate collection action may be taken;

(C) that in any case in which an eligible organization is related to another organization by common ownership or control, a consolidated financial statement shall be filed and that the allowable costs for such organization may not include costs for the types of expenses otherwise reimbursable under this subchapter, in excess of those which would be determined to be reasonable in accordance with regulations (providing for limiting reimbursement to costs rather than charges to the eligible organization by related organizations and owners) issued by the Secretary; and

(D) that in any case in which compensation is paid by an eligible organization substantially in excess of what is normally paid for similar services by similar practitioners (regardless of method of compensation), such compensation may as appropriate be considered to constitute a distribution of profits.

(5) (A) After August 5, 1997, the Secretary may not enter into a reasonable cost reimbursement contract under this subsection (if the contract is not in effect as of August 5, 1997), except for a contract with an eligible organization which, immediately previous to entering into such contract, had an agreement in effect under section 1395l(a)(1)(A) of this title.

(B) Subject to subparagraph (C), the Secretary shall approve an application for a modification to a reasonable cost contract under this section in order to expand the service area of such contract if—

(i) such application is submitted to the Secretary on or before September 1, 2003; and

(ii) the Secretary determines that the organization with the contract continues to meet the requirements applicable to such organizations and contracts under this section.

(C)(i) Subject to clause (ii), a reasonable cost reimbursement contract under this subsection may be extended or renewed indefinitely.

(ii) For any period beginning on or after January 1, 2013, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area during the entire previous year was within the service area of—

(I) 2 or more MA regional plans described in clause (iii), provided that all such plans are not offered by the same Medicare Advantage organization; or

(II) 2 or more MA local plans described in clause (iii), provided that all such plans are
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(iii) A plan described in this clause for a year for a service area is a plan described in section 1395w–21(a)(2)(A)(i) of this title if the service area for the year meets the following minimum enrollment requirements:

(1) Each contract under this section shall be for a term of at least one year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term; except that in accordance with procedures established under paragraph (9), the Secretary may at any time terminate any such contract or may impose the intermediate sanctions described in paragraph (6)(B) or (6)(C) (whichever is applicable) on the eligible organization if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner substantially inconsistent with the efficient and effective administration of this section; or

(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f) of this section.

(2) The effective date of any contract executed pursuant to this section shall be specified in the contract.

(3) Each contract under this section—

(A) shall provide that the Secretary, or any person or organization designated by him—

(i) shall have the right to inspect or otherwise evaluate (I) the quality, appropriateness, and timeliness of services performed under the contract and (II) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(ii) shall have the right to audit and inspect any books and records of the eligible organization that pertain (I) to the ability of the organization to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(B) shall require the organization with a risk-sharing contract to provide (and pay for)

written notice in advance of the contract’s termination, as well as a description of alternatives for obtaining benefits under this subchapter, to each individual enrolled under this section with the organization; and

(C)(i) shall require the organization to comply with subsections (a) and (c) of section 300e–17 of this title (relating to disclosure of certain financial information) and with the requirement of section 300e(c)(8) of this title (relating to liability arrangements to protect members);

(ii) shall require the organization to provide and supply information (described in section 1395cc(b)(2)(C)(i) of this title) in the manner such information is required to be provided or supplied under that section;

(iii) shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties; and

(D) shall contain such other terms and conditions not inconsistent with this section (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(4) The Secretary may not enter into a risk-sharing contract with an eligible organization if a previous risk-sharing contract with that organization under this section was terminated at the request of the organization within the preceding five-year period, except in circumstances which warrant special consideration, as determined by the Secretary.

(5) The authority vested in the Secretary by this section may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this subchapter.

(6)(A) If the Secretary determines that an eligible organization with a contract under this section—

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this section in excess of the premiums permitted;

(iii) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this section;

(iv) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this section) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(v) misrepresents or falsifies information that is furnished—

See References in Text note below.
(I) to the Secretary under this section, or
(II) to an individual or to any other entity under this section;
(vi) fails to comply with the requirements of
subsection (g)(6)(A) of this section or para-
graph (B); or
(vii) in the case of a risk-sharing contract,
employs or contracts with any individual or
terms, or (v) any patient or other patient or
entity that is excluded from participation
under this subchapter under section 1320a–7 or
1320a–7a of this title for the provision of health
or administrative services or employs or con-
tracts with any entity for the provision (di-
rectly or indirectly) through such an excluded
individual or entity of such services;
the Secretary may provide, in addition to any
other remedies authorized by law, for any of the
remedies described in subparagraph (B).
(B) The remedies described in this subpara-
graph are—
(i) civil money penalties of not more than
$25,000 for each determination under subpara-
graph (A) or, with respect to a determination
under clause (iv) or (v) of such subpara-
graph, of not more than $100,000 for each such
determination, plus, with respect to a determi-
mination under subparagraph (A)(ii), double
the excess amount charged in violation of such
subparagraph (and the excess amount charged
shall be deducted from the penalty and re-
turned to the individual concerned), and plus,
with respect to a determination under sub-
paragraph (A)(iv), $15,000 for each individual
not enrolled as a result of the practice in-
volved,
(ii) suspension of enrollment of individuals
under this section after the date the Secretary
notifies the organization of a determination
under subparagraph (A) and until the Sec-
retary is satisfied that the basis for such de-
termination has been corrected and is not
likely to recur, or
(iii) suspension of payment to the organiza-
tion under this section for individuals enrolled
after the date the Secretary notifies the orga-
ization of a determination under subpara-
graph (A) and until the Secretary is satisfied
that the basis for such determination has been
corrected and is not likely to recur.
(C) In the case of an eligible organization for
which the Secretary makes a determination
under paragraph (1), the basis of which is not
described in subparagraph (A), the Secretary may
apply the following intermediate sanctions:
(i) Civil money penalties of not more than
$25,000 for each determination under paragraph
(1) if the deficiency that is the basis of the
determination has directly adversely affected (or
has the substantial likelihood of adversely af-
fected) an individual covered under the orga-
nization’s contract.
(ii) Civil money penalties of not more than
$10,000 for each week beginning after the initi-
ation of procedures by the Secretary under
paragraph (9) during which the deficiency that
is the basis of a determination under para-
graph (1) exists.
(iii) Suspension of enrollment of individuals
under this section after the date the Secretary
notifies the organization of a determination
under paragraph (1) and until the Secretary is
satisfied that the deficiency that is the basis
for the determination has been corrected and
is not likely to recur.
(D) The provisions of section 1320a–7a of this
title (other than subsections (a) and (b)) shall
apply to a civil money penalty under subpara-
grah (B)(i) or (C)(i) in the same manner as such
provisions apply to a civil money penalty or pro-
ceeding under section 1320a–7a of this title.
(7)(A) Each risk-sharing contract with an eli-
gable organization under this section shall pro-
vide that the organization will maintain a writ-
ten agreement with a utilization and quality
control peer review organization (which has a
contract with the Secretary under part B of sub-
chapter XI of this chapter for the area in which
the eligible organization is located) or with an
entity selected by the Secretary under section
1320c–3(a)(4)(C) of this title under which the re-
view organization will perform functions under
section 1320c–3(a)(4)(B) of this title and section
1320c–3(a)(14) of this title (other than those per-
formed under contracts described in section
1395c(c)(1)(F) of this title) with respect to serv-
ces furnished by the eligible organization, for
which payment may be made under this sub-
chapter.
(B) For purposes of payment under this sub-
chapter, the cost of such agreement to the eli-
gable organization shall be considered a cost in-
curred by a provider of services in providing cov-
ered services under this subchapter and shall be
paid directly by the Secretary to the review or-
ganization on behalf of such eligible organiza-
in accordance with a schedule established
by the Secretary.
(C) Such payments—
(i) shall be transferred in appropriate pro-
portions from the Federal Hospital Insurance
Trust Fund and from the Supplementary Med-
ical Insurance Trust Fund, without regard to
amounts appropriated in advance in appropri-
ation Acts, in the same manner as transfers are
made for payment for services provided di-
rectly to beneficiaries, and
(ii) shall not be less in the aggregate for
such organizations for a fiscal year than the
amounts the Secretary determines to be suffi-
cient to cover the costs of such organizations’
conducting activities described in subpara-
graph (A) with respect to such eligible organi-
izations under part B of subchapter XI of this
chapter.
(8)(A) Each contract with an eligible organiza-
tion under this section shall provide that the or-
ganization may not operate any physician in-
centive plan (as defined in subparagraph (B)) un-
less the following requirements are met:
(i) No specific payment is made directly or
indirectly under the plan to a physician or
physician group as an inducement to reduce or
limit medically necessary services provided
with respect to a specific individual enrolled
with the organization.
(ii) If the plan places a physician or physi-
cian group at substantial financial risk (as de-
termined by the Secretary) for services not
provided by the physician or physician group,
the organization—
(I) provides stop-loss protection for the physician or group that is adequate and appropriate, based on standards developed by the Secretary that take into account the number of physicians placed at such substantial financial risk in the group or under the plan and the number of individuals enrolled with the organization who receive services from the physician or the physician group, and

(II) conducts periodic surveys of both individuals enrolled and individuals previously enrolled with the organization to determine the degree of access of such individuals to services provided by the organization and satisfaction with the quality of such services.

(iii) The organization provides the Secretary with descriptive information regarding the plan, sufficient to permit the Secretary to determine whether the plan is in compliance with the requirements of this subparagraph.

(B) In this paragraph, the term "physician incentive plan" means any compensation arrangement between an eligible organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization.

(9) The Secretary may terminate a contract with an eligible organization under this section or may impose the intermediate sanctions described in paragraph (6) on the organization in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary first provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under paragraph (1) and the organization fails to develop or implement such a plan;

(B) in deciding whether to impose sanctions, the Secretary considers aggravating factors such as whether an organization has a history of deficiencies or has not taken action to correct deficiencies the Secretary has brought to the organization's attention;

(C) there are no unreasonable or unnecessary delays between the finding of a deficiency and the imposition of sanctions; and

(D) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before imposing any sanction or terminating the contract.

(j) Payment in full and limitation on actual charges; physicians, providers of services, or renal dialysis facilities not under contract with organization

(1) In the case of physicians' services or renal dialysis services described in paragraph (2) which are furnished by a participating physician or provider of services or renal dialysis facility to an individual enrolled with an eligible organization under this section and enrolled under part B of this subchapter, the applicable participation agreement is deemed to provide that the physician or provider of services or renal dialysis facility will accept as payment in full from the eligible organization the amount that would be payable to the physician or provider of services or renal dialysis facility under part B of this subchapter and reduced for the individual under such part, if the individual were not enrolled with an eligible organization under this section.

(B) In the case of physicians' services described in paragraph (2) which are furnished by a nonparticipating physician, the limitations on actual charges for such services otherwise applicable under part B of this subchapter (to services furnished by individuals not enrolled with an eligible organization under this section) shall apply in the same manner as such limitations apply to services furnished to individuals not enrolled with such an organization.

(2) The physicians' services or renal dialysis services described in this paragraph are physicians' services or renal dialysis services which are furnished to an enrollee of an eligible organization under this section by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization.

(k) Risk-sharing contracts

(1) Except as provided in paragraph (2)—

(A) on or after the date standards for Medicare+Choice organizations and plans are first established under section 1395w–26(b)(1) of this title, the Secretary shall not enter into any risk-sharing contract under this section with an eligible organization; and

(B) for any contract year beginning on or after January 1, 1999, the Secretary shall not renew any such contract.

(2) An individual who is enrolled in part B of this subchapter only and is enrolled in an eligible organization with a risk-sharing contract under this section on December 31, 1998, may continue enrollment in such organization in accordance with regulations described in section 1395w–26(b)(1) of this title.

(3) Notwithstanding subsection (a) of this section, the Secretary shall provide that payment amounts under risk-sharing contracts under this section for months in a year (beginning with January 1998) shall be computed—

(A) with respect to individuals entitled to benefits under both parts A and B of this subchapter, by substituting payment rates under section 1395w–23(a) of this title for the payment rates otherwise established under subsection (a) of this section, and

(B) with respect to individuals only entitled to benefits under part B of this subchapter, by substituting an appropriate proportion of such rates (reflecting the relative proportion of payments under this subchapter attributable to such part) for the payment rates otherwise established under subsection (a) of this section.

(4) The following requirements shall apply to eligible organizations with risk-sharing contracts under this section in the same manner as they apply to Medicare+Choice organizations under part C of this subchapter:

(A) Data collection requirements under section 1395w–23(a)(3)(B) of this title.
that the organization—’’ in introductory provisions, added subpars. (A) to (C), and struck out former subpars. (A) to (C) which read as follows:

‘‘(A) has failed substantially to carry out the contract,

‘‘(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this section, or

‘‘(C) no longer substantially meets the applicable conditions of subsections (b), (c), (e), and (f) of this section.

Subsec. (i)(6)(B). Pub. L. 104–191, § 215(a)(4), struck out concluding provisions which read as follows: ‘‘The provisions of section 1320a–7a of this title (other than subsection (a)) shall not apply to a civil money penalty or proceeding under section 1320a–7a(a) of this title.’’


Subsec. (i)(7)(A). Pub. L. 104–191, § 215(b), substituted ‘‘a written agreement’’ for ‘‘an agreement’’.


Subsec. (c)(5)(B). Pub. L. 103–236 inserted at end ‘‘In applying sections 405(b) and 405(g) of this title as provided in this subparagraph, and in applying section 405(i) of this title thereto, any reference therein to the Secretary or the Department of Health and Human Services, respectively.’’

1990—Subsec. (a)(1)(E). Pub. L. 101–508, § 4204(e)(1), designated paragraphs (f) and (i) as (f) and added cl. (ii). Subsec. (a)(6). Pub. L. 101–508, § 4204(c)(2), substituted ‘‘subsections (c)(2)(B)(ii) and (c)(7)’’ for ‘‘subsection (c)(7)’’ of this section.

Subsec. (c)(2). Pub. L. 101–508, § 4204(c)(1), designated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) and former cl.s. (1) and (ii) as cl.s. (1) and (ii) respectively, and added subpar. (B).


Subsec. (i)(6)(A)(vi). Pub. L. 101–508, § 4204(a)(2), inserted ‘‘or paragraph (8)’’ after ‘‘(g)(6)(A) of this section’’.


Subsec. (j)(1)(A). Pub. L. 101–508, § 4204(d)(1)(A), substituted ‘‘physicians’ services or renal dialysis services’’ for ‘‘physicians’ services’’.’’

Subsec. (j)(2). Pub. L. 101–508, § 4204(d)(1)(B), substituted ‘‘physicians’ services or renal dialysis services’’ for ‘‘physicians’ services’’ in two places and substituted ‘‘and during a period of not longer than four years’’ for ‘‘and during a period of not longer than four years’’.

Subsec. (a)(5). Pub. L. 101–234, § 201(a), added cl. (ii) and struck out former cl. (1) which read as follows: ‘‘For each area served by more than one eligible organization under this section, the Secretary (after consultation with such organizations) shall establish a single 30-day period each year during which all eligible organizations serving the area must provide for open enrollment under this section. The Secretary shall determine annual per capita rates under subsection (a)(1)(A) of this section in a manner that assures that individuals enrolling during such a 30-day period will not have premium charges increased or any additional benefits decreased for 12 months beginning on the date the individual’s enrollment becomes effective. An eligible organization may provide for such other open enrollment period or periods as it deems proper consistent with this section.’’


1988—Subsec. (a)(5). Pub. L. 100–360, § 202(f)(1), amended second sentence generally. Prior to amendment, second sentence read as follows: ‘‘The portion of the payment to the organization for a month to be paid by the latter trust fund shall be equal to 200 percent of the sum of—

(A) the product of (i) the number of such individuals for the month who have attained age 65, and (ii) the monthly actuarial rate for supplementary medical insurance for the month as determined under section 1395(r)(1) of this title, and

(B) the product of (i) the number of such individuals for the month who have not attained age 65, and (ii) the monthly actuarial rate for supplementary medical insurance for the month as determined under section 1395(r)(4) of this title.’’


Subsec. (c)(4)(F). Pub. L. 100–360, § 411(c)(1), realigned margin with left margin of subpar. (G).

Subsec. (e)(1). Pub. L. 100–360, § 202(f)(1), inserted at end ‘‘The preceding sentence shall be applied separately with respect to covered outpatient drugs.’’

Subsec. (f)(3). Pub. L. 100–647 redesignated par. (4) as (3) and struck out former par. (3) which read as follows: ‘‘(A) An eligible organization described in subparagraph (B) may elect, for purposes of enrollment and residency requirements under this section and for determining the compliance of a subdivision, subsidiary, or affiliate described in subparagraph (B)(iii) with the requirement of paragraph (1) for the period before October 1, 1992, to have members described in subparagraph (B)(iii) who receive services through the subdivision, subsidiary, or affiliate considered to be members of the parent organization.

(B) An eligible organization described in this subparagraph is an eligible organization which—

(i) is described in section 1396(a)(2)(B)(iii) of this title; and

(ii) has members who have a collectively bargained contractual right to obtain health benefits from the organization.

(iii) elects to provide benefits under a risk-sharing contract to individuals residing in a service area, who
have a collectively bargained contractual right to obtain benefits from the organization, through a subdivision, subsidiary, or affiliate which itself is an eligible organization serving the area and which is owned or controlled by the parent eligible organization; and

"(iv) has assumed any risk of insolvency and quality assurance with respect to individuals receiving benefits through such a subdivision, subsidiary, or affiliate."

Subsec. (i)(3)(A). Pub. L. 100–130–60, § 411(c)(6), formerly § 411(c)(5), as redesignated by Pub. L. 100–485, § 608(d)(19)(C), inserted "enrollment and residency requirements under this section and for" after "for purposes of" and substituted "described in subparagraph (B)(iii) who receives services through the subdivision" for "of the subdivision".

Subsec. (i)(4). Pub. L. 100–647 redesignated par. (4) as (3).


Subsec. (1)(B). Pub. L. 100–360, § 411(c)(4)(B), substituted "or proceeding under section 1320c–3(a)(4)(C) of this title, each", inserted "or with an entity selected by the Secretary under section 1320c–3(a)(4)(C) of this title after "located", and substituted "which the review organization for "which the peer review organization".

Subsec. (i)(7)(B). Pub. L. 100–203, § 4039(h)(8)(C), as added by Pub. L. 100–360, § 411(c)(3), substituted "the review organization" for "the peer review organization".


Pub. L. 99–272, § 9211(d), inserted ", and shall publish not later than September 7 before the calendar year concerned after "The Secretary shall annually determine" in introductory provisions.

Subsec. (a)(3). Pub. L. 99–272, § 9211(a)(2), substituted "Subject to subsection (c)(7) of this section, payments" for "Payments".

Subsec. (a)(5). Pub. L. 99–272, § 9211(a)(3), substituted "Subject to subsection (c)(7) of this section, if" for "If".

Subsec. (c)(3)(B). Pub. L. 99–272, § 9211(b), substituted "the date on which" for "a full calendar month after", and inserted provision at end that in the case of an individual's termination of enrollment, the organization shall provide the individual with a copy of the written request for termination of enrollment and a written explanation of the period (ending on the effective date of the termination) during which the individual continues to be enrolled with the organization and may not receive benefits under this chapter other than through the organization.

Subsec. (c)(3)(C). Pub. L. 99–272, § 9211(c), inserted provisions at end that no brochures, application forms, or other promotional or informational material may be distributed by an organization to (or for the use of) individuals eligible to enroll with the organization under this section unless at least 45 days before its distribution, the organization has submitted the material to the Secretary for review and the Secretary has not disapproved the material or the organization shall disapprove such material if the Secretary determines, in the Secretary's discretion, that the material is materially inaccurate or misleading or otherwise makes a material misrepresentation.


Subsec. (f)(2). Pub. L. 99–509, § 9312(c)(1), struck out "if the Secretary determines that" after "imposed by paragraph (1) only", added new subpars. (A) and (B), and struck out former subpars. (A) and (B) which read as follows:

"(A) special circumstances warrant such modification or waiver, and

"(B) the eligible organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this chapter or under a State plan approved under subchapter XIX of this chapter."

to subsection (i) of this section for provisions that such requirement not apply with respect to any health maintenance organization for such period not to exceed three years from the date such organization first enters into an agreement with the Secretary pursuant to subsection (i) of this section, as the Secretary may permit.

Subsec. (i)(8)(B). Pub. L. 94–460, §201(c), substituted "other than with respect to out-of-area services and, in the case of an organization which has entered into a risk-sharing contract with the Secretary pursuant to paragraph (2)(A), the cost of providing any member with basic health services the aggregate value of which exceeds $5,000 in any year" for "(Other than those with respect to out-of-area services)".


1973—Subsec. (a)(3)(A)(ii). Pub. L. 93–233, §18(m), struck out "`, with the amount of savings being proportional to the losses absorbed and not yet offset'" at end.

Subsec. (g)(2). Pub. L. 93–233, §18(n), substituted "portion of its premium rate or other charges" for "portion" and "shall not exceed" for "may not exceed", and struck out cl. (i) designation preceding "the actuarial value" and provisions reading "less (ii)" the actuarial value of other charges made in lieu of such deductible and coinsurance, respectively.

1972—Subsec. (i). Pub. L. 92–603, §278(b)(3), substituted "skilled nursing facility" for "extended care facility" and "skilled nursing facilities" for "extended care facilities".

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 103–183, set out as a note under section 1395w–2 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Section 215(c) of Pub. L. 104–191 provided that: "The amendments made by this section [amending this section] shall apply with respect to contract years beginning on or after January 1, 1997."

Amendment by section 231(g) of Pub. L. 104–191 applicable to acts or omissions occurring on or after Jan. 1, 1997, see section 110(a) of Pub. L. 104–191, set out as a note under section 1320a–7a of this title.

EFFECTIVE DATE OF 1994 AMENDMENTS

Amendment by Pub. L. 103–422 effective as if included in the enactment of Pub. L. 101–508, see section 157(b)(8) of Pub. L. 103–422, set out as a note under section 1395y of this title.


EFFECTIVE DATE OF 1990 AMENDMENTS

Section 4204(c)(2) of Pub. L. 101–312, as amended by Pub. L. 103–422, title I, §157(b)(3), Oct. 31, 1994, 108 Stat. 4422, provided that: "The amendments made by this subsection [amending this section] shall apply with respect to national coverage determinations that are not incorporated in the determination of the per capita rate of payment for individuals enrolled for years beginning with 1991 with an eligible organization which has entered into a risk-sharing contract under section 1976 of the Social Security Act [this section]."

4442, provided that: "The amendments made by paragraph (1) [amending this section] shall apply with respect to enrollments effected on or after January 1, 1990.''

Section 4208(o)(2) of Pub. L. 101–508, as amended by Pub. L. 103–43, title I, §157(b)(5), Oct. 31, 1994, 108 Stat. 4442, provided that: "The amendments made by paragraph (1) [amending this section] shall apply with respect to enrollees in an eligible organization under a health benefit plan operated, sponsored, or contributed to, by any individual's employer or former employer (or the former employer of any individual's spouse) on or after January 1, 1991.''

Amendment by section 4208(o)(1) of Pub. L. 101–508 applicable to contracts under this section and payments under section 1955(a)(1)(A) of this title as of the first day of the first month beginning more than 1 year after Nov. 5, 1988, see section 4208(o)(2) of Pub. L. 101–508, set out as a note under section 1395 of this title.

Effective Date of 1989 Amendments

Section 6208(b)(2) of Pub. L. 101–239 provided that: "The amendments made by paragraph (1) [amending this section] shall take effect 60 days after the date of the enactment of this Act [Dec. 19, 1989].''

Section 6221(b)(2) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section] shall apply to services furnished on or after April 1, 1990.''

Section 6221(o)(3) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section and repealing provisions set out as notes below] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].''

Amendment by section 201(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1323a–7a of this title.

Amendment by section 202(a) of Pub. L. 101–234 effective Jan. 1, 1990, and applicable to premiums for months beginning after Dec. 31, 1989, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

Effective Date of 1988 Amendments

Section 8412(b) of Pub. L. 100–647 provided that: "The amendments made by subsection (a) [amending this section] shall not apply to contracts in effect on the date of the enactment of this Act [Nov. 10, 1988] or extended, or made significant progress towards compliance, the Secretary may extend such waiver. If the Secretary determines that the organization has complied, or made significant progress towards compliance, the Secretary may extend such waiver. If the Secretary determines that the organization has not complied with such schedule, the organization shall make, and continue to make, reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by the Secretary of Health and Human Services. If the Secretary determines that the organization has complied, or made significant progress towards compliance, with such schedule of compliance, the Secretary may extend such waiver. If the Secretary determines that the organization has not complied with such schedule, the Secretary may provide for a sanction described in section 1876(f)(3) of the Social Security Act [subsec. (f)(3) of this section]."

"(ii) does not meet the requirements for such modification or waiver under the amendment made by paragraph (1) of this subsection, the organization shall make, and continue to make, reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by the Secretary of Health and Human Services. If the Secretary determines that the organization has complied, or made significant progress towards compliance, with such schedule of compliance, the Secretary may extend such waiver. If the Secretary determines that the organization has not complied with such schedule, the Secretary may provide for a sanction described in section 1876(f)(3) of the Social Security Act [subsec. (f)(3) of this section] (as amended by this section) effective with respect to individuals enrolling with the organization after the date the Secretary notifies the organization of such noncompliance.

"(D) Treatment of Certain Waivers.—In the case of an eligible organization (or successor organization) that—

"(i) as of the date of the enactment of this Act, has been granted, under paragraph (2) of section 1876(f) of the Social Security Act [subsec. (f)(2) of this section], a modification or waiver of the requirements imposed by paragraph (1) of that section, but

"(ii) does not meet the requirements for such modification or waiver under the amendment made by paragraph (1) of this subsection, the organization shall make, and continue to make, reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by the Secretary of Health and Human Services. If the Secretary determines that the organization has complied, or made significant progress towards compliance, with such schedule of compliance, the Secretary may extend such waiver. If the Secretary determines that the organization has not complied with such schedule, the Secretary may provide for a sanction described in section 1876(f)(3) of the Social Security Act [subsec. (f)(3) of this section] (as amended by this section) effective with respect to individuals enrolling with the organization after the date the Secretary notifies the organization of such noncompliance.

Amendment by section 211(c)(3) of Pub. L. 100–359 applicable to enrollments effected on or after Jan. 1, 1990, see section 211(d) of Pub. L. 100–359, set out as a note under section 1386r of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(c)(1), (3), (4), (6), (e)(3) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a note under section 1386r of this title. Effective Date note under section 106 of Title I, General Provisions.

Effective Date of 1987 Amendment

Section 4011(a)(2) of Pub. L. 100–203 provided that: "The amendment made by paragraph (1) [amending this section] shall apply with respect to contracts entered into or renewed on or after the date of enactment of this Act [Dec. 22, 1987].''

Section 4011(b)(2) of Pub. L. 100–203 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to contracts entered into or renewed on or after the date of the enactment of this Act [Dec. 22, 1987].''

Section 4012(d) of Pub. L. 100–203 provided that: "The amendments made by subsections (a) and (b) [amending this section and section 1395cc of this title] shall apply to admissions occurring on or after April 1, 1988, or, if later, the earliest date the Secretary can provide the information required under subsection (c) [set out as a note below] in machine-readable form.

Section 4013(b) of Pub. L. 100–203, which provided the effective date for amendment made by section 4013(a) of Pub. L. 100–203, was omitted in the general amendment of section 4913 of Pub. L. 100–360, title IV, §411(c)(3), July 1, 1988, 102 Stat. 733.

Effective Date of 1986 Amendments

Section 8955(b)(1)(B) of Pub. L. 99–514 provided that: "The amendment made by subparagraph (A) [amending this section] shall apply to determinations of per capita payment rates for 1987 and subsequent years."
review of the organization to determine the organization’s compliance with the quality assurance requirements of section 1876(c)(6) of such Act [subsec. (c)(6) of this section]; and

“(iii) after January 1, 1990, if the organization receives an unfavorable review under clause (ii), the Secretary, after notice to the organization of the unfavorable review and an opportunity to correct any deficiencies identified during the review, may provide for the sanction described in section 1876(c)(3) of such Act [subsec. (c)(3) of this section] effective with respect to individuals enrolling with the organization after the date the Secretary notifies the organization that the organization is not in compliance with the requirements of section 1876(c)(6) of such Act.”

Section 9312(d)(2) of Pub. L. 99–509 provided that: “The amendment made by paragraph (1) [amending this section] shall apply to risk-sharing contracts under section 1876 of the Social Security Act [this section] as of April 1, 1986, for such changes in the risk-sharing contracts which constitute a hardship for the organization involved.

Section 9312(e)(2) of Pub. L. 99–509 provided that: “The amendments made by paragraph (1) [amending this section] shall apply to contracts as of January 1, 1987.

Section 9333(e)(3)(B) of Pub. L. 99–509, as amended by Pub. L. 100–203, title IV, § 4039(h)(9)(C), as added by Pub. L. 100–366, title IV, §411(c)(3), July 1, 1988, 102 Stat. 776, provided that: “The amendment made by paragraph (2) [amending this section] shall apply to risk-sharing contracts with eligible organizations, under section 1876 of the Social Security Act [this section], as of April 1, 1986, for such changes in the risk-sharing contracts (as defined in paragraph (3)(A) of this section) that resulting from the application of such amendment to eligible health maintenance organizations.

The monthly premium for June 1983 shall apply to individuals enrolled under parts A and B of title XVIII of the Social Security Act effective as if originally included as a part of this section by amendment made by section 1395ww of this title.

Effective Date of 1984 Amendment

Section 2350(d) of Pub. L. 98–369 provided that: “The amendments made by this section (amending this section and enacting provisions set out as notes under this section) shall become effective on the date of the enactment of this Act [July 18, 1984].

Amendment by section 2354(e)(1) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed under the provisions of law involved before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

Effective Date of 1983 Amendments; Transitional Rule

Amendment by section 602(g) 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 section 606(a)(3)(H) of Pub. L. 98–21 applicable to premiums for months beginning with January 1984, but for months after June 1983 and before January 1984, the monthly premium for June 1983 shall apply to individuals enrolled under parts A and B of this subchapter, see section 606(c) of Pub. L. 98–21, set out as a note under section 1395ww of this title.

Amendment by section 308(b)(12) of Pub. L. 97–448 effective as if originally included as a part of this section by amendment made by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, see section 308(c)(2) of Pub. L. 97–448, set out as a note under section 4201 of this title.

Effective Date of 1982 Amendment

Section 114(c) of Pub. L. 97–248, as amended by Pub. L. 98–369, div. B, title III, §2354(c)(3)(A), (B), July 18, 1984, 98 Stat. 617, set out as a note under title XVIII of the Social Security Act [this subchapter] at the time the organization first enters into a new risk-sharing contract (as defined in paragraph (3)(D)) unless—

“(1) the individual requests at any time that the amendment apply, or

“(ii) the Secretary determines at any time that the amendment should apply to all members of the organization because of administrative costs or other administrative burdens involved and so informs in advance each affected member of the eligible organization;

“(B) with respect to services furnished by an eligible organization during the five-year period beginning on the initial effective date, and before such initial effective date the organization enters into an existing risk-sharing contract, unless the organization requests that the amendment apply earlier; or
“(C) with respect to services furnished by an eligible organization during the period of an existing demonstration project if on the initial effective date the organization was furnishing services pursuant to that project and if the project concludes after such date.

“(2)(A) In the case of an eligible organization which has in effect an existing cost contract (as defined in paragraph (3)(A) on the initial effective date, the organization may receive payment under a new risk-sharing contract with respect to a current, nonrisk Medicare enrollee (as defined in subparagraph (C)) only to the extent that the organization enrolls, for each such enrollee, two new Medicare enrollees (as defined in subparagraph (D)). The selection of those current nonrisk Medicare enrollees with respect to whom payment may be so received under a new risk-sharing contract shall be made in a nonbiased manner.

“(B) Subparagraph (A) shall not be construed to prevent an eligible organization from providing for enrollment, on a basis described in subsection (a)(6) of section 1876 of the Social Security Act [subsec. (a)(6) of this section] (as amended by this Act [Pub. L. 97–248]), other than under a reasonable cost reimbursement contract, of current, nonrisk Medicare enrollees and from providing such enrollees with some or all of the additional benefits described in section 1876(g)(2) of the Social Security Act [subsec. (g)(2) of this section] (as amended by this Act [Pub. L. 97–248], but (except as provided in subparagraph (A))—

“(i) payment to the organization with respect to such enrollees shall only be made in accordance with the terms of a reasonable cost reimbursement contract, and

“(ii) no payment may be made under section 1876 of such Act [this section] with respect to such enrollees for any such additional benefits.

Individuals enrolled with the organization under this subparagraph shall be considered to be individuals enrolled with the organization for the purpose of meeting the requirement of section 1876(g)(2) of the Social Security Act [subsec. (g)(2) of this section] (as amended by this Act [Pub. L. 97–248]).

“(C) For purposes of this paragraph, the term ‘current, nonrisk Medicare enrollee’ means, with respect to an organization, an individual who on the initial effective date—

“(i) is enrolled with that organization under an existing cost contract, and

“(ii) is entitled to benefits under part A and enrolled under part B, or enrolled in part B, of title XVIII of the Social Security Act [this subchapter].

“(D) For purposes of this paragraph, the term ‘new Medicare enrollee’ means, with respect to an organization, an individual who—

“(i) is enrolled with the organization after the date the organization first enters into a new risk-sharing contract,

“(ii) at the time of such enrollment is entitled to benefits under part A, or enrolled in part B, of title XVIII of the Social Security Act [this subchapter], and

“(iii) was not enrolled with the organization at the time the individual became entitled to benefits under part A, or to enroll in part B, of such title [this subchapter].

“(E) The preceding provisions of this paragraph shall not to [sic] apply to payments made for current, nonrisk Medicare enrollees for months beginning with April 1987.

“(F) For purposes of this subsection:

“(A) The term ‘existing cost contract’ means a contract which is entered into under section 1876 of the Social Security Act [this section], as in effect before the initial effective date. The term ‘existing demonstration project’ means a demonstration project under section 402(a) of the Social Security Amendments of 1967 [section 1395b–1(a) of this title] or under section 222(a) of the Social Security Amendments of 1972 [section 222(a) of Pub. L. 92–603, set out as a note under section 1395b–1 of this title], relating to the provision of services for which payment may be made under title XVIII of the Social Security Act [this subchapter].

“(B) The term ‘new risk-sharing contract’ means a contract entered into under section 1876(g) of the Social Security Act [subsec. (g) of this section], as amended by this Act [Pub. L. 97–248].

“(C) The term ‘reasonable cost reimbursement contract’ means a contract entered into under section 1876(h) of such Act [subsec. (h) of this section], as amended by this Act, or reimbursement on a reasonable cost basis under section 1833(a)(1)(A) of such Act [section 1395(a)(1)(A) of this title].

“(D) The term ‘new Medicare enrollee’ means a demonstration project if on the initial effective date the organization was furnishing services pursuant to that project and if the project concludes after such date.

“(E) The term ‘reasonably certain’ means a contract entered into under section 1876(a)(4) of the Social Security Act [subsec. (a)(4) of this section], as amended by this Act [Pub. L. 97–248] has been developed and can be implemented to assure actuarial equivalence in the estimation of adjusted average per capita costs under that program, whichever is later.’’

**Effective Date of 1978 Amendment**

Amendment by Pub. L. 95–292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility’s or provider’s first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as a note under section 426 of this title.

**Effective Date of 1976 Amendment**

Section 201(e) of Pub. L. 94–460 provided that: “The amendments made by this section (amending this section) shall be effective with respect to contracts entered into between the Secretary and health maintenance organizations under section 1876 of the Social Security Act [this section] on and after the second day of the first calendar month which begins more than 30 days after the date of enactment of this Act [Oct. 8, 1976].”

**Effective Date of 1973 Amendment**

Section 182(c)(3) of Pub. L. 92–503 provided that: “The amendments made by this section (amending this section) shall be effective with respect to services provided after June 30, 1973.”
under this section] shall be effective with respect to services provided on or after July 1, 1973.’’

**REPORT ON IMPACT**

Section 4002(b)(2)(B) of Pub. L. 105–33 provided that: ‘‘By not later than January 1, 2001, the Secretary of Health and Human Services shall submit to Congress a report that analyzes the potential impact of termination of reasonable cost reimbursement contracts, pursuant to the amendment made by subparagraph (A), on Medicare beneficiaries enrolled under such contracts and on the Medicare program. The report shall include such recommendations regarding any extension or transition with respect to such contracts as the Secretary deems appropriate.’’

**TRANSITION RULE FOR PPO ENROLLMENT**

Section 4002(h) of Pub. L. 105–33 provided that: ‘‘In applying subsection (g)(1) of section 1876 of the Social Security Act (42 U.S.C. 1395mm) to a risk-sharing contract entered into with an eligible organization that is a provider-sponsored organization (as defined in section 1855(d)(1) of such Act [section 1395w–25(d)(1) of this title], as inserted by section 5001 (4001)) for a contract year beginning on or after January 1, 1998, there shall be substituted for the minimum number of enrollees provided under such section the minimum number of enrollees permitted under section 1857(b)(1) of such Act [1395w–27(b)(1) of this title] (as so inserted).’’

**REQUIREMENTS WITH RESPECT TO ACTUARIAL EQUIVALENT OF AAPCC**


‘‘(1)(A) Not later than October 1, 1995, the Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) shall submit a proposal to the Congress that provides for revisions to the payment method to be applied in years beginning with 1997 for organizations with a risk-sharing contract under section 1876(g) of the Social Security Act [subsec. (g) of this section].

‘‘(B) In proposing the revisions required under subparagraph (A), the Secretary shall consider—

‘‘(i) the difference in costs associated with Medicare beneficiaries with differing health status and demographic characteristics; and

‘‘(ii) the effects of using alternative geographic classifications on the determinations of costs associated with beneficiaries residing in different areas.

‘‘(2) Not later than 3 months after the date of submittal of the proposal under paragraph (1), the Comptroller General shall review the proposal and shall report to Congress on the appropriateness of the proposed modifications.

[Amendment by section 222(g) of Pub. L. 104–316 to section 4204(b)(4), (5) of Pub. L. 101–508, set out above, as amended by Pub. L. 103–432.]

**STUDY OF CHIROPRACTIC SERVICES**

Section 4204(f) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §157(b)(6), Oct. 31, 1994, 108 Stat. 4442, directed Secretary to conduct a study of the extent to which health maintenance organizations with contracts under section 1876 of the Social Security Act (this section) make available to enrollees entitled to benefits under title XVIII of such Act (this subchapter) chiropractic services that are covered under such title, such study to examine the arrangements under which such services are made available and the types of practitioners furnishing such services to such enrollees and to be based on contracts entered into or renewed on or after Jan. 1, 1991, and before Jan. 1, 1993, with Secretary to issue a report to Congress on results of the study not later than Jan. 1, 1993, including recommendations with respect to any legislative and regulatory changes determined necessary by Secretary to ensure access to such services.

**EFFECT ON STATE LAW**

Conscientious objections of health care provider under State law unaffected by enactment of subsection (c)(8) of this section, see section 4204(c) of Pub. L. 101–508, set out as a note under section 1395sc of this title.

**NOTICE OF METHODOLOGY USED IN MAKING ANNOUNCEMENTS UNDER SUBSECTION (a)(1)(A)**

Section 6206(a)(2) of Pub. L. 101–239 provided that: ‘‘Before July 1, 1996, the Secretary of Health and Human Services shall provide for notice to eligible organizations of the methodology used in making the announcement under section 1876(a)(1)(A) of the Social Security Act [subsec. (a)(1)(A) of this section] for 1996.’’

**ADJUSTMENT OF CONTRACTS WITH PREPARED HEALTH PLANS**

Section 203(b) of Pub. L. 101–234 provided that: ‘‘Notwithstanding any other provision of this Act [see this title], the amendments made by this Act (other than the repeal of sections 1833(c)(5) and 1834(c)(6) of the Social Security Act [sections 1395c(c)(5) and 1395m(c)(6) of this title]) shall not apply to risk-sharing contracts, for contract year 1990—

‘‘(1) with eligible organizations under section 1876 of the Social Security Act [this section], or

‘‘(2) with health maintenance organizations under section 1876(1)(2)(A) of such Act [subsec. (1)(2)(A) of this section] (as in effect before February 1, 1985), under section 420(a) of the Social Security Amendments of 1967 [section 1395b–1(a) of this title], or under section 222(a) of the Social Security Amendments of 1972 [Pub. L. 92–603, set out as a note under section 1395b–1 of this title].’’

**ADJUSTMENT OF CONTRACTS WITH PREPARED HEALTH PLANS**


‘‘(1) modify contracts under section 1876 of the Social Security Act (this section), for portions of contract years occurring after December 31, 1988, to take into account the amendments made by this Act [see Short Title of 1988 Amendment note under section 1301 of this title]; and

‘‘(2) require such organizations and organizations paid under section 1833(a)(1)(A) of such Act [section 1395b(a)(1)(A) of this title] to make appropriate adjustments (including adjustments in premiums and benefits) in the terms of their agreements with Medicare beneficiaries to take into account such amendments.

The Secretary shall also provide for appropriate modifications of contracts with health maintenance organizations under section 1876(1)(2)(A) of the Social Security Act [subsec. (1)(2)(A) of this section] (as in effect before February 1, 1985), under section 420(a) of the Social Security Amendments of 1967 [section 1395b–1(a) of this title], or under section 222(a) of the Social Security Amendments of 1972 [42 U.S.C. 1395b–1 note], for portions of contract years occurring after December 31, 1988, so as to apply to such organizations and contracts the requirements imposed by the amendments made by this Act upon an organization with a risk-sharing contract under section 1876 of the Social Security Act.’’

**PROVISION OF MEDICARE DRG RATES FOR CERTAIN PAYMENTS AND DATA ON INPATIENT COST PASS-THROUGH ITEMS**

Section 4012(c) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(c)(2)(B), July 1, 1988, 102 Stat. 773, provided that: ‘‘The Secretary of Health and
Human Services shall provide (in machine readable form) to eligible organizations under section 1876 of the Social Security Act [this section] Medicare DRG rates for payments required by the amendment made by subsection (a) [amending section 1395cc of this title] and data on cost pass-through items for all inpatient services provided to Medicare beneficiaries enrolled with such organizations.

**MEDICARE PAYMENT DEMONSTRATION PROJECTS**


"(a) Medicare Insured Group Demonstration Projects.

"(1) The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) may provide for capitation demonstration projects (in this subsection referred to as ‘projects’) with an entity which is an eligible organization with a contract with the Secretary under section 1876 of the Social Security Act [this section] that such meets the restrictions and requirements of this subsection. The Secretary may not approve a project unless it meets the requirements of this subsection.

"(2) The Secretary may not conduct more than 3 projects and may not expend, from funds under title XVIII of the Social Security Act [this subchapter], more than $600,000,000 in any fiscal year for all such projects.

"(3) The per capita rate of payment under a project—

"(A) may be based on the adjusted average per capita cost (as defined in section 1876(a)(4) of the Social Security Act [subsec. (a)(4) of this section]) determined only with respect to the group of individuals involved (rather than with respect to Medicare beneficiaries generally), but

"(B) the rate of payment may not exceed the lesser of—

"(i) 95 percent of the adjusted average per capita cost described in subparagraph (A), or

"(ii) (1) in the 4th year or 5th year of a project, 115 percent of the adjusted average per capita cost (as defined in section 1876(a)(4) of such Act [subsec. (a)(4) of this section]) for classes of individuals described in section 1876(a)(1)(B) of such Act [subsec. (a)(1)(B) of this section], or

"(II) in any subsequent year of a project, 95 percent of the adjusted average per capita cost (as defined in section 1876(a)(4) [subsec. (a)(4) of this section]) for such classes.

"(4) If the payment amounts made to a project are greater than the costs of the project (as determined by the Secretary or, if applicable, on the basis of adjusted community rates described in section 1876(e)(3) of the Social Security Act [subsec. (e)(3) of this section]), the project—

"(A) may retain the surplus, but not to exceed 5 percent of the average adjusted per capita cost determined in accordance with paragraph (3)(A), and

"(B) with respect to any additional surplus not retained by the project, shall apply such surplus to additional benefits for individuals served by the project or return such surplus to the Secretary.

"(5) Enrollment under the project shall be voluntary. Individuals enrolled with the project may terminate such enrollment as of the beginning of the first calendar month following the date on which the request is made for such termination. Upon such termination, such individuals shall retain the same rights to other health benefits that such individuals would have had if they had never enrolled with the project without any exclusion or waiting period for pre-existing conditions.

"(6) The requirements of—

"(A) subsection (c)(3)(C) (relating to dissemination of information),

"(B) subsection (c)(3)(E) (annual statement of rights),

"(C) subsection (c)(5) (grievance procedures),

"(D) subsection (c)(6) (on-going quality),

"(E) subsection (g)(6) (relating to prompt payment of claims),

"(F) subsection (i)(3)(A) and (B) (relating to access to information and termination notices),

"(G) subsection (i)(6) (relating to providing necessary services), and

"(H) subsection (i)(7) (relating to agreements with peer review organizations).

"(7) The benefits provided under a project must be at least actuarially equivalent to the combination of the benefits available under title XVIII of the Social Security Act [this subchapter] and the benefits available through any alternative plans in which the individual can enroll through the employer. The project shall guarantee the actuarial value of benefits available under the employer plan for the duration of the project.

"(8) A project shall comply with all applicable State laws.

"(9) The Secretary may not authorize a project unless the entity offering the project demonstrates to the satisfaction of the Secretary that it has the necessary financial reserves to pay for any liability for benefits under the project (including those liabilities for health benefits under Medicare and any supplemental benefits).

"(10) The Comptroller General shall monitor projects under this subsection and shall report periodically (not less often than once every year) to the Committee on Finance of the Senate and the Committee on Energy and Commerce and Committee on Ways and Means of the House of Representatives on the status of such projects and the effect on such projects of the requirements of this section and shall submit a final report to each such committee on the results of such projects.

"(b) Payment Methodology Reform Demonstration Projects.

"(1) The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) is specifically authorized to conduct demonstration projects under this subsection for the purpose of testing alternative payment methodologies pertaining to capitation payments under title XVIII of the Social Security Act [this subchapter], including—

"(A) computing adjustments to the average per capita cost under section 1876 of such Act [this section] on the basis of health status or prior utilization of services, and

"(B) accounting for geographic variations in cost in the adjusted average per capita costs applicable to an eligible organization under such section which differs from payments currently provided on a county-by-county basis.

"(2) No project may be conducted under this subsection—

"(A) with an entity which is not an eligible organization (as defined in section 1875(b) of the Social Security Act [subsec. (b) of this section]), and

"(B) unless the project meets all the requirements of subsections (c) and (i)(3) of section 1876 of such Act [subsecs. (c) and (i)(3) of this section].

"(3) There are authorized to be appropriated to carry out projects under this subsection $5,000,000 in each of fiscal years 1989 and 1990.

"(c) Application of Provisions. The provisions of subsection (a) and the first sentence of subsection (b) of section 1876 [section 1395b–1(a)(2), (b) of this title] shall apply to the demonstration projects under this section in the same manner as they apply to experiments under subsection (a)(1) of that section. [For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual,
semiannual, or other regular periodic report listed in
House Document No. 103–7 (in which the requirement to
report not less than once every year to certain commit-
tees of Congress under section 4010(a)(10) of Pub. L.
100–203, set out above, is listed on page 9, see section
3003 of Pub. L. 104–66, as amended, set out as a note
under section 1113 of Title 31, Money and Finance.]  

GAO STUDY AND REPORTS ON MEDICARE CAPITATION

Section 4017 of Pub. L. 100–203 directed Comptroller
General to conduct a study on medicare capitation rates
that would include an analysis and assessment of the
current method for computing per capita rates of
payment under section 1876 of the Social Security Act
(this section), including the method for determining the
United States per capita cost; the method for establish-
ishing relative costs for geographic areas and the data
used to establish age, sex, and other weighting factors;
ways to refine the calculation of adjusted average per
capita costs under section 1876 of such Act, including
making adjustments for health status or prior utiliza-
tion of services and improvements in the definition of
geographic areas; the extent to which individuals en-
rolled with organizations with a risk-sharing contract
with the Secretary under section 1876 of such Act differ
in utilization and cost from fee-for-service beneficiaries
and ways for modifying enrollment patterns through
program changes or for reflecting the differences rates
through group experience rating or other means; appro-
aches for limiting the liability of the contracting
organization under section 1876 of such Act in cata-
strophic cases; ways of establishing capitation rates on
a basis other than fee-for-service experience in areas
with high prepaid market penetration; and methods for
providing the rate levels necessary to maintain access to
quality prepaid services in rural or medically under-
served areas, while maintaining cost savings; and di-
rected Comptroller General, not later than January 1 of
1989 and 1990, to submit to Congress interim reports
on the progress of the study and, not later than Jan. 1,
1991, a final report on the results of such study.

DEMONSTRATION PROJECTS TO PROVIDE PAYMENT ON A
PREPAID, CAPITATED BASIS FOR COMMUNITY NURSING
AND AMBULATORY CARE FURNISHED TO MEDICARE BENEFICIARIES

2763, 2763A–566, provided that:

"(a) EXTENSION.—Notwithstanding any other provi-
sion of law, any demonstration project conducted under
section 4019 of the Omnibus Budget Reconciliation Act of
1395mm note) and conducted for the additional period
of 2 years as provided for under section 4019 of BBA
(Pub. L. 105–33, set out as a note below), shall be con-
ducted for an additional period of 2 years.

"(b) TERMS AND CONDITIONS.—

"(1) JANUARY THROUGH SEPTEMBER 2000.—For the 9-
month period beginning with January 2000, any such
demonstration project shall be conducted under the
same terms and conditions as applied to such dem-
stration during 1999.

"(2) OCTOBER 2000 THROUGH DECEMBER 2001.—For the
15-month period beginning with October 2000, any such
demonstration project shall be conducted under the
same terms and conditions as applied to such dem-
stration during 1999, except that the following modifi-
cations shall apply:

"(A) BASIC CAPITATION RATE.—The basic capita-
tion rate paid for services covered under the project
(other than case management services) per enrollee
per month and furnished during—

"(i) the period beginning with October 1, 2000,
and ending with December 31, 2000, shall be deter-
mined by actually adjusting the actual capitation
rate paid for such services in 1999 for infla-
tion, utilization, and other changes to the CNO
service package, and by reducing such adjusted
capitation rate by 10 percent in the case of the
demonstration sites located in Arizona, Min-
nesota, and Illinois, and 15 percent for the demo-
stration site located in New York; and

"(ii) 2001 shall be determined by actuarily ad-
justing the capitation rate determined under
clause (i) for inflation, utilization, and other
changes to the CNO service package.

"(B) TARGETED CASE MANAGEMENT FEE.—Effective
October 1, 2000—

"(i) the case management fee per enrollee per
month for—

"(I) the period described in subparagraph
(A)(i) shall be determined by actuarily adjust-
ing the case management fee for 1999 for infla-
tion; and

"(II) 2001 shall be determined by actuarily ad-
justing the amount determined under sub-
clause (I) for inflation; and

"(ii) such case management fee shall be paid
only for enrollees who are classified as moder-
cately frail or frail pursuant to criteria estab-
lished by the Secretary.

"(C) GREATER UNIFORMITY IN CLINICAL FEATURES
AMONG SITES.—Each project shall implement for
each site—

"(i) protocols for periodic telephonic contact
with enrollees based on—

"(I) the results of such standardized written
health assessment; and

"(II) the application of appropriate care plan-
ing approaches;

(ii) disease management programs for targeted
diseases (such as congestive heart failure, arthri-
tis, diabetes, and hypertension) that are highly
prevalent in the enrolled populations;

(iii) systems and protocols to track enrollees
through hospitalizations, including pre-admission
planning, concurrent management during inpa-
tient hospital stays, and post-discharge assess-
ment, planning, and follow-up; and

(iv) standardized patient educational mate-
rials for specified diseases and health conditions.

"(D) QUALITY IMPROVEMENT.—Each project shall
implement at each site once during the 15-month
period—

"(i) enrollee satisfaction surveys; and

(ii) reporting on specified quality indicators
for the enrolled population.

"(e) EVALUATION.—

"(1) PRELIMINARY REPORT.—Not later than July 1,
2001, the Secretary of Health and Human Services
shall submit to the Committees on Ways and Means
and Commerce (now Energy and Commerce) of the
House of Representatives and the Committee on Fi-
nance of the Senate a preliminary report that—

"(A) evaluates such demonstration projects for
the period beginning July 1, 1997, and ending De-
cember 31, 1999, on a site-specific basis with respect
to the impact on per beneficiary spending, specific
health utilization measures, and enrollee satisfac-
tion; and

"(B) includes a similar evaluation of such
projects for the portion of the extension period that

"(2) FINAL REPORT.—The Secretary shall submit a
final report to such Committees on such demonstra-
tion projects not later than July 1, 2002. Such report
shall include the same elements as the preliminary
report required by paragraph (1), but for the period
after December 31, 1999.

"(3) METHODOLOGY FOR SPENDING COMPARISONS.—
An evaluation of the impact of the demonstration
projects on per beneficiary spending included in such
reports shall include a comparison of—

"(A) data for all individuals who—

"(i) were enrolled in the demonstration
projects as of the first day of the period under
evaluation; and
“(ii) were enrolled for a minimum of 6 months thereafter; with

“(B) data for a matched sample of individuals who are enrolled under part B of title XVIII of the Social Security Act [part B of this subchapter] and are not enrolled in such a project, or in a Medicare+Choice plan under part C of such title [part C of this subchapter], a plan offered by an eligible organization under section 1876 of such Act [this section], or a health care prepayment plan under section 1383(a)(1)(A) of such Act (section 1395(aa)(1)(A) of this title).”


Section 4019 of Pub. L. 105–33 provided that: “Notwithstanding any other provision of law, demonstration projects conducted under section 4079 of the Omnibus Budget Reconciliation Act of 1997 [Pub. L. 100–203, set out as a note below] may be conducted for an additional period of 2 years, and the deadline for any report required relating to the results of such projects shall not be later than 6 months before the end of such additional period.”

Section 6079 of Pub. L. 100–203, as amended by Pub. L. 100–395, title IV, §§411(b)(6), July 1, 1988, 102 Stat. 727, provided that:

“(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall enter into an agreement with not less than four eligible organizations submitting applications under this section to conduct demonstration projects to provide payment on a prepaid, capitated basis for community nursing and ambulatory care furnished to any individual entitled to benefits under part A and enrolled under part B of title XVIII of the Social Security Act [part B of this subchapter] (other than an individual medically determined to have end-stage renal disease) who resides in the geographic area served by the organization and enrolled with such organization in accordance with subsection (c)(2)).”

“(b) DEFINITIONS OF COMMUNITY NURSING AND AMBULATORY CARE AND ELIGIBLE ORGANIZATION.—As used in this section:

“(1) The term ‘community nursing and ambulatory care’ means the following services:

“(A) Part-time or intermittent nursing care furnished by or under the supervision of registered professional nurses.

“(B) Physical, occupational, or speech therapy.

“(C) Social and related services supportive of a plan of ambulatory care.

“(D) Part-time or intermittent services of a home health aide.

“(E) Medical supplies (other than drugs and biologicals) and durable medical equipment while under a plan of care.

“(F) Medical and other health services described in paragraphs (2)(H)(ii) and (5) through (9) of section 1395m of the Social Security Act [section 1395m(a)(2)(H)(ii), (5)–(9) of this title].

“(G) Rural health clinic services described in section 1395mm(a)(1)(C) of such Act [section 1395mm(a)(1)(C) of this title].

“(H) Certain other related services listed in section 1915(c)(4)(B) of such Act [section 1396n(c)(4)(B) of this title] to the extent the Secretary finds such services are appropriate to prevent the need for institutionalization of a patient.

“(2) The term ‘eligible organization’ means a public or private entity, organized under the laws of any State, which meets the following requirements:

“(A) The entity (or a division or part of such entity) is primarily engaged in the direct provision of community nursing and ambulatory care.

“(B) The entity provides that all services are furnished by qualified staff and are coordinated by a registered professional nurse.

“(C) The entity provides that all nursing care (including services of home health aids) is furnished by or under the supervision of a registered nurse.

“(D) The entity provides that all services are furnished by qualified staff and are coordinated by a registered professional nurse.

“(E) The entity has policies governing the furnishing of community nursing and ambulatory care that are developed by registered professional nurses in cooperation with (as appropriate) other professionals.

“(F) The entity maintains clinical records on all patients.

“(G) The entity has protocols and procedures to assure, when appropriate, timely referral to or consultation with other health care providers or professionals.

“(H) The entity complies with applicable State and local laws governing the provision of community nursing and ambulatory care to patients.

“(I) The requirements of subparagraphs (B), (D), and (E) of section 1876(b)(2) of the Social Security Act [42 U.S.C. 1395mm(b)(2), (D), (E)];

“(j) AGREEMENTS WITH ELIGIBLE ORGANIZATIONS TO CONDUCT DEMONSTRATION PROJECTS.—

“(1) The Secretary may not enter into an agreement with an eligible organization to conduct a demonstration project under this section unless the organization meets the requirements of this subsection and subsection (e) with respect to members enrolled with the organization under this section.

“(2) The organization shall have an open enrollment period for the enrollment of individuals under this section. The duration of such period of enrollment and any other requirement pertaining to enrollment or termination of enrollment shall be specified in the agreement with the organization.

“(3) The organization must provide to members enrolled with the organization under this section, through providers and other persons that meet the applicable requirements of titles XVII and XIX of the Social Security Act [this subchapter and subchapter XIX of this chapter], community nursing and ambulatory care (as defined in subsection (b)(1)) which is generally available to individuals residing in the geographic area served by the organization, except that the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered.

“(4) The organization must make arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals under the demonstration project conducted under this section, which program (A) stresses health outcomes and (B) provides review by health care professionals of the process followed in the provision of such health care services.

“(5) Section 1876(c)(5) of the Social Security Act [subsec. (c)(5) of this section] shall apply to organizations under this section in the same manner as it applies to organizations under section 1876 of such Act.

“(6) The organization must have arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for health care services it provides to such individuals under the demonstration project conducted under this section, which program (A) stresses health outcomes and (B) provides review by health care professionals of the process followed in the provision of such health care services.

“(7) Under a demonstration project under this section—

“(A) the Secretary could require the organization to provide financial or other assurances (including financial risk-sharing) that minimize the inappropriate substitution of other services under title XVIII of such Act (this subchapter) for community nursing services; and

“(B) if the Secretary determines that the organization has failed to perform in accordance with the
requirements of the project (including meeting financial responsibility requirements under the project, any pattern of disproportionate or inappropriate institutionalization) the Secretary shall, after notice, terminate the project.

“(d) Determination of Per Capita Payment Rates—

“(1) The Secretary shall determine for each 12-month period in which a demonstration project is conducted under this section, and shall announce (in a manner intended to provide notice to interested parties) not later than three months before the beginning of such period, with respect to each eligible organization conducting a demonstration project under this section, a per capita rate of payment for each class of individuals who are enrolled with such organization who are entitled to benefits under part A and enrolled under part B of title XVIII of the Social Security Act (part A and part B of this subchapter).

“(2)(A) Except as provided in paragraph (3), the per capita rate of payment under paragraph (1) shall be determined in accordance with this paragraph.

“(B) The Secretary shall define appropriate classes of members, based on age, disability status, and such other factors as the Secretary determines to be appropriate, so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such classes, if such changes will improve the determination of actuarial equivalence.

“(C) The per capita rate of payment under paragraph (1) for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in subparagraph (D)) for that class.

“(D) For purposes of subparagraph (C), the term ‘adjusted average per capita cost’ means the average per capita amount that the Secretary estimates in advance (on the basis of actual experience, or retrospective actuarial equivalent based upon an adequate sample and other information and data, in a geographic area served by an eligible organization or in a similar area, with appropriate adjustments to assure actuarial equivalence) would be payable in any contract year for those services covered under parts A and B of title XVIII of the Social Security Act (parts A and B of this subchapter) and types of expenses otherwise reimbursable under such parts A and B which are described in subparagraphs (A) through (G) of subsection (b)(1) (including administrative costs incurred by organizations in accordance with sections 1816 and 1842 of such Act (sections 1395h and 1395u of this title), if the services were to be furnished by other than an eligible organization.

“(3) The Secretary shall, in consultation with providers, health policy experts, and consumer groups develop capitation-based reimbursement rates for such classes of individuals entitled to benefits under part A and enrolled under part B of the Social Security Act [probably means parts A and B of this subchapter] and types of expenses otherwise reimbursable under such parts A and B which are defined in subparagraphs (A) through (G) of subsection (b)(1) (including administrative costs incurred by organizations in accordance with sections 1816 and 1842 of such Act (sections 1395h and 1395u of this title), if the services were to be furnished by other than an eligible organization.

“(4)(A) In the case of an eligible organization conducting a demonstration project under this section, the Secretary shall make monthly payments in advance and in accordance with the rate determined under paragraph (2) or (3), except as provided in subsection (e)(3)(B), to the organization for each individual enrolled with the organization.

“(B) The amount of payment under paragraph (2) or (3) may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

“(5) The payment to an eligible organization under this section for individuals enrolled under this section with the organization and entitled to benefits under part A and enrolled under part B of the Social Security Act shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund established under such Act (chapter 11) in such proportions from each such trust fund as the Secretary deems to be fair and equitable taking into consideration benefits attributable to such parts A and B, respectively.

“(6) During any period in which an individual is enrolled with an eligible organization conducting a demonstration project under this section, only the eligible organization (and no other individual or person) shall be entitled to receive payments from the Secretary under this title [probably means title XVIII of the Social Security Act, this subchapter] for community nursing and ambulatory care (as defined in subsection (b)(1)) furnished to the individual.

“(e) Restriction on Premiums, Deductibles, Copayments, and Coinsurance—

“(1) In no case may the portion of an eligible organization’s premium rate and the actuarial value of its deductibles, coinsurance, and copayments charged (with respect to community nursing and ambulatory care) to individuals who are enrolled under this section with the organization, exceed the actuarial value of the coinsurance and deductibles that would be applicable on the average to individuals enrolled with the organization for this section with the organization (or, if the Secretary finds that adequate data are not available to determine that actuarial value, the actuarial value of the coinsurance and deductibles applicable on the average to individuals in the area of the State, or in the United States, eligible to enroll under this section with the organization, or other appropriate data) and entitled to benefits under part A and enrolled under part B of the Social Security Act [probably means parts A and B of title XVIII of this Act, this subchapter] if they were not members of an eligible organization.

“(2) If the eligible organization provides to its members enrolled under this section services in addition to community nursing and ambulatory care, election of coverage for such additional services shall be optional for such members and such organization shall furnish such members with information on the portion of its premium rate or other charges applicable to such additional services. In no case may the sum of—

“(A) the portion of such organization’s premium rate charged, with respect to such additional services, to members enrolled under this section, and

“(B) the actuarial value of its deductibles, coinsurance, and copayments, charged with respect to such services to such members,

“exceed the adjusted community rate for such services (as defined in section 1876(e)(3) of the Social Security Act [subsec. (e)(3) of this section]).

“(3)(A) Subject to paragraphs (B) and (C), each agreement to conduct a demonstration project under this section shall provide that if—

“(i) the adjusted community rate, referred to in paragraph (2), for community nursing and ambulatory care covered under parts A and B of title XVIII of the Social Security Act [parts A and B of this subchapter] (as reduced for the actuarial value of the coinsurance and deductibles applicable under those parts) for members enrolled under this section with the organization,

“is less than

“(ii) the average of the per capita rates of payment to be made under subsection (d)(1) at the beginning of the 12-month period (as determined on such basis as the Secretary determines appropriate) described in such subsection for members enrolled under this section with the organization, the eligible organization shall provide to such members the additional benefits described in section 1876(e)(3) of the Social Security Act [subsec. (g)(3) of this section] which are selected by the eligible organization and which the Secretary finds are at least
equal in value to the difference between that average per capita payment and the adjusted community rate (as so reduced).

"(B) Subparagraph (A) shall not apply with respect to any organization which elects to receive a lesser payment to the extent that there is no longer a difference between the average per capita payment and adjusted community rate (as so reduced).

"(C) An organization conducting a demonstration project under this section may provide (with the approval of the Secretary) that a part of the value of such additional benefits under subparagraph (A) be withheld and reserved by the Secretary as provided in section 1876(g)(5) of the Social Security Act [subsec. (g)(5) of this section].

"(4) The provisions of paragraphs (3), (5), and (6) of section 1876(g) of the Social Security Act [subsec. (g)(3), (5), and (6) of this section] shall apply in the same manner to agreements under this section as they apply to risk-sharing contracts under section 1876 of such Act, and, for this purpose, any reference in such paragraphs to paragraph (2) is deemed a reference to paragraph (3) of this subsection.

"(5) Section 1876(e)(4) of the Social Security Act [subsec. (e)(4) of this section] shall apply to eligible organizations under this section in the same manner as it applies to eligible organizations under section 1876 of such Act.

"(f) Commencement and Duration of Projects.—Each demonstration project under this section shall begin not later than July 1, 1989, and shall be conducted for a period of three years.

"(g) Report.—Not later than January 1, 1992, the Secretary shall submit to the Congress a report on the results of the demonstration projects conducted under this section.

STUDY OF AAPCC AND ACR

Section 9312(g) of Pub. L. 99–509 directed Secretary of Health and Human Services to provide, through contract with an appropriate organization, for a study of the methods by which the adjusted average per capita cost ("AAPCC", as defined in subsec. (a)(4) of this section) can be refined to more accurately reflect the average cost of providing care to different classes of patients, and the adjusted community rate ("ACR", as defined in subsec. (e)(3) of this section) can be refined, with Secretary to submit to Congress, by not later than Jan. 1, 1988, specific legislative recommendations concerning methods by which the calculation of the AAPCC and the ACR could be refined.

ALLOWING MEDICARE BENEFICIARIES TO DISENROLL AT LOCAL SOCIAL SECURITY OFFICES

Section 9312(h) of Pub. L. 99–509 provided that: "The Secretary of Health and Human Services shall provide in this section may disenroll, on and after June 1, 1987, at any local office of the Social Security Administration."

USE OF RESERVE FUNDS

Section 9312(i) of Pub. L. 99–509 provided that: "Notwithstanding any provision of section 1878(g)(5) of the Social Security Act [42 U.S.C. 1395mm(g)(5)] to the contrary, funds reserved by an eligible organization under section 1876 of the Social Security Act [this section] may disenroll, on and after June 1, 1987, at any local office of the Social Security Administration."

PHASE-IN OF ENROLLMENT PERIOD BY SECRETARY

Section 2350(a)(2) of Pub. L. 98–369 provided that: "The Secretary of Health and Human Services may phase in, over a period of not longer than three years, the application of the amendments made by paragraph (1) [amending this section] to all applicable areas in the United States if the Secretary determines that it is not administratively feasible to establish a single 30-day open enrollment period for all such applicable areas before the end of the period.

STABILIZATION FUND; ESTABLISHMENT LIMITATION: USER'S REPORT TO CONGRESS

Section 2350(b)(3), (4) of Pub. L. 98–369, as amended by Pub. L. 100–203, title IV, § 4013, Dec. 22, 1987, 101 Stat. 1330–61; Pub. L. 100–369, title IV, § 411(c)(3), July 1, 1988, 102 Stat. 773, prohibited Secretary of Health and Human Services from approving the establishment of a stabilization fund by an eligible organization under subsec. (g)(5) of this section for any contract period beginning later than Sept. 30, 1990, and directed Secretary to report to Congress with respect to such funds by eligible organizations under subsec. (g)(5) of this section and to assess the need for such funds not later than 54 months after July 1984, prior to repeal by Pub. L. 101–239, title VI, § 4121(c)(1), Dec. 19, 1989, 103 Stat. 2250.

STUDY OF ADDITIONAL BENEFITS SELECTED BY ELIGIBLE ORGANIZATIONS

Section 114(d) of Pub. L. 97–248 directed Secretary of Health and Human Services to conduct a study of the additional benefits selected by eligible organizations pursuant to this section, with the Secretary to report to Congress within 24 months of the initial effective date (as defined in subsec. (c)(4) of section 114 of Pub. L. 97–248) with respect to the findings and conclusions made as a result of such study.

STUDY EVALUATING THE EXTENT OF, AND REASONS FOR, TERMINATION BY MEDICARE BENEFICIARIES OF MEMBERSHIP IN ORGANIZATIONS WITH CONTRACTS UNDER THIS SECTION

Section 114(e) of Pub. L. 97–248 directed Secretary of Health and Human Services to conduct a study evaluating the extent of, and reasons for, the termination by Medicare beneficiaries of their memberships in organizations with contracts under section 1876 of the Social Security Act (this section), with the Secretary to submit an interim report to Congress, within two years after the initial effective date (as defined in subsec. (c)(4) of section 114 of Pub. L. 97–248), and a final report within five years after such date containing the respective interim and final findings and conclusions made as a result of such study.

REIMBURSEMENT FOR SERVICES

Section 2360(b) of Pub. L. 97–339 provided that: "(1) Notwithstanding the provisions of section 1814 and section 1333 of the Social Security Act [sections 1395f and 1395i of this title], any health maintenance organization which has entered into a contract with the Secretary pursuant to section 1876 of such Act [this section] shall, for the duration of such contract, (except as provided in paragraph (2)) be entitled to reimbursement only as provided in section 1376 of such Act [this section] for individuals who are members of such organizations.

"(2) With respect to individuals who are members of organizations which have entered into a risk-sharing contract with the Secretary pursuant to subsection (1)(2)(A) [of this section] prior to July 1, 1973, and who, although eligible to have payment made pursuant to section 1876 of such Act [this section] for services rendered to them, chose (in accordance with regulations) not to have such payment made pursuant to such section, the Secretary shall, for a period not to exceed three years commencing on July 1, 1973, pay to such organization on the basis of an interim per capita rate, determined in accordance with the provisions of section 1876(a)(2) of such Act [subsec. (a)(2) of this section], with appropriate actuarial adjustments to reflect the difference in utilization of out-of-plan services, which would have been considered sufficiently reasonable and necessary under the rules of the health maintenance
organization to be provided by that organization, between such individuals and individuals who are enrolled with such organization pursuant to section 1397 of such Act [this section]. Payments under this paragraph shall be subject to retroactive adjustment at the end of each contract year as provided in paragraph (3). "(3) If the Secretary determines that the per capita cost of any such organization in any contract year for providing services to individuals described in paragraph (2), when combined with the cost of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such year for providing out-of-plan services to such individuals, is less than or greater than the adjusted average per capita cost (as defined in section 1876(a)(3) of such Act [subsec. (a)(3) of this section] of providing such services, the resulting savings shall be apportioned between such organization and such Trust Funds, or the resulting losses shall be absorbed by such organization, in the manner prescribed in section 1397a(a)(3) of such Act [subsec. (a)(3) of this section]."

§ 1395nn. Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified

For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

(b) General exceptions to both ownership and compensation arrangement prohibitions

Subsection (a)(1) of this section shall not apply in the following cases:

(1) Physicians’ services

In the case of physicians’ services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4) of this section) as the referring physician.

(2) In-office ancillary services

In the case of services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies)—

(A) that are furnished—

(i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are directly supervised by the physician or by another physician in the group practice, and

(ii)(I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians’ services unrelated to the furnishing of designated health services, or

(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice—

(aa) for the provision of some or all of the group’s clinical laboratory services, or

(bb) for the centralized provision of the group’s designated health services (other than clinical laboratory services), unless the Secretary determines other terms and conditions under which the provision of such services does not present a risk of program or patient abuse, and

(B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member under a billing number assigned to the group practice, or by an entity that is wholly owned by such physician or such group practice, if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse. Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1395x(d) of this title) who furnish such services in the area in which such individual resides.

(3) Prepaid plans

In the case of services furnished by an organization—

(A) with a contract under section 1395mm of this title to an individual enrolled with the organization,
(B) described in section 1395(f)(1)(A) of this title to an individual enrolled with the organization,
(C) receiving payments on a prepaid basis, under a demonstration project under section 1395b-1(a) of this title or under section 222(a) of the Social Security Amendments of 1972, to an individual enrolled with the organization,
(D) that is a qualified health maintenance organization (within the meaning of section 300(e)(2)(A) of this title) to an individual enrolled with the organization, or
(E) that is a Medicare+Choice organization under part C of this subchapter that is offering a coordinated care plan described in section 1395w-21(a)(2)(A) of this title to an individual enrolled with the organization.

(4) Other permissible exceptions

In the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.

(5) Electronic prescribing

An exception established by regulation under section 1395w-104(e)(6) of this title.

(c) General exception related only to ownership or investment prohibition for ownership in publicly traded securities and mutual funds

Ownership of the following shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public and which are—

(A)(i) securities listed on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis, or

(ii) traded under an automated interdealer quotation system operated by the National Association of Securities Dealers, and

(B) in a corporation that had, at the end of the corporation’s most recent fiscal year, or on average during the previous 3 fiscal years, stockholder equity exceeding $75,000,000.

(2) Ownership of shares in a regulated investment company as defined in section 851(a) of the Internal Revenue Code of 1986, if such company had, at the end of the company’s most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding $75,000,000.

(d) Additional exceptions related only to ownership or investment prohibition

The following, if not otherwise excepted under subsection (b) of this section, shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Hospitals in Puerto Rico

In the case of designated health services provided by a hospital located in Puerto Rico.

(2) Rural providers

In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by an entity, if—

(A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area;

(B) effective for the 18-month period beginning on December 8, 2003, the entity is not a specialty hospital (as defined in subsection (h)(7) of this section); and

(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).

(3) Hospital ownership

In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if—

(A) the referring physician is authorized to perform services at the hospital;

(B) effective for the 18-month period beginning on December 8, 2003, the hospital is not a specialty hospital (as defined in subsection (h)(7) of this section);

(C) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital); and

(D) the hospital meets the requirements described in subsection (i)(1) not later than 18 months after March 23, 2010.

(e) Exceptions relating to other compensation arrangements

The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B) of this section:

(1) Rental of office space; rental of equipment

(A) Office space

Payments made by a lessee to a lessor for the use of premises if—

(i) the lease is set out in writing, signed by the parties, and specifies the premises covered by the lease,

(ii) the space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee, except that the lessee may make payments for the use of space consisting of common areas if such payments do not exceed the lessee’s pro rata share of expenses for such space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using such common areas,

(iii) the lease provides for a term of rental or lease for at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
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(5) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Equipment

Payments made by a lessee of equipment to the lessor of the equipment for the use of the equipment if—

(i) the lease is set out in writing, signed by the parties, and specifies the equipment covered by the lease,

(ii) the equipment rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental and is used exclusively by the lessee when being used by the lessee,

(iii) the lease provides for a term of rental or lease of at least 1 year,

(iv) the rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(v) the lease would be commercially reasonable even if no referrals were made between the parties, and

(vi) the lease meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Bona fide employment relationships

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

(A) the employment is for identifiable services,

(B) the amount of the remuneration under the employment—

(i) is consistent with the fair market value of the services, and

(ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals or other business generated between the parties,

(C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and

(D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

(3) Personal service arrangements

(A) In general

Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a non-profit blood center) if—

(i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,

(ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,

(iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,

(iv) the term of the arrangement is for at least 1 year,

(v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B)(i), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law, and

(vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Physician incentive plan exception

(i) In general

In the case of a physician incentive plan (as defined in clause (ii)) between a physician and an entity, the compensation may be determined in a manner (through a withhold, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, if the plan meets the following requirements:

(I) No specific payment is made directly or indirectly under the plan to a physician or a physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the entity.

(II) In the case of a plan that places a substantial financial risk as determined by the Secretary pursuant to section 1395mm(i)(8)(A)(ii) of this title, the plan complies with any requirements the Secretary may impose pursuant to such section.

(III) Upon request by the Secretary, the entity provides the Secretary with access to descriptive information regarding the plan, in order to permit the Secretary to determine whether the plan is in compliance with the requirements of this clause.

(ii) "Physician incentive plan" defined

For purposes of this subparagraph, the term “physician incentive plan” means
any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the entity.

(4) Remuneration unrelated to the provision of designated health services

In the case of remuneration which is provided by a hospital to a physician if such remuneration does not relate to the provision of designated health services.

(5) Physician recruitment

In the case of remuneration which is provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, if—

(A) the physician is not required to refer patients to the hospital,

(B) the amount of the remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician, and

(C) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(6) Isolated transactions

In the case of an isolated financial transaction, such as a one-time sale of property or practice, if—

(A) the requirements described in subparagraphs (B) and (C) of paragraph (2) are met with respect to the entity in the same manner as they apply to an employer, and

(B) the transaction meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(7) Certain group practice arrangements with a hospital

(A) In general

An arrangement between a hospital and a group under which designated health services are provided by the group but are billed by the hospital if—

(i) with respect to services provided to an inpatient of the hospital, the arrangement is pursuant to the provision of inpatient hospital services under section 1395x(b)(3) of this title,

(ii) the arrangement began before December 19, 1989, and has continued in effect without interruption since such date,

(iii) with respect to the designated health services covered under the arrangement, substantially all of such services furnished to patients of the hospital are furnished by the group under the arrangement,

(iv) the arrangement is pursuant to an agreement that is set out in writing and that specifies the services to be provided by the parties and the compensation for services provided under the agreement,

(v) the compensation paid over the term of the agreement is consistent with fair market value and the compensation per unit of services is fixed in advance and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,

(vi) the compensation is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the entity, and

(vii) the arrangement between the parties meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(B) Payments by a physician for items and services

Payments made by a physician—

(A) to a laboratory in exchange for the provision of clinical laboratory services, or

(B) to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.

(f) Reporting requirements

Each entity providing covered items or services for which payment may be made under this subchapter shall provide the Secretary with the information concerning the entity’s ownership, investment, and compensation arrangements, including—

(1) the covered items and services provided by the entity, and

(2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A) of this section), or with a compensation arrangement (as described in subsection (a)(2)(B) of this section), in the entity, or whose immediate relatives have such an ownership or investment interest who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides services for which payment may be made under this subchapter very infrequently.

(g) Sanctions

(1) Denial of payment

No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section.

(2) Requiring refunds for certain claims

If a person collects any amounts that were billed in violation of subsection (a)(1) of this section, the person shall be liable to the indi-
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(3) Civil money penalty and exclusion for improper claims

Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under paragraph (1) or for which a refund has not been made under paragraph (2) shall be subject to a civil money penalty of not more than $15,000 for each such service. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than $100,000 for each such arrangement or scheme. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(5) Failure to report information

Any person who is required, but fails, to meet a reporting requirement of subsection (f) of this section is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(6) Advisory opinions

(A) In general

The Secretary shall issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section. Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) Application of certain rules

The Secretary shall, to the extent practicable, apply the rules under subsections (b)(3) and (b)(4) of this section and take into account the regulations promulgated under subsection (b)(5) of section 1320a–7d of this title in the issuance of advisory opinions under this paragraph.

(C) Regulations

In order to implement this paragraph in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(D) Applicability

This paragraph shall apply to requests for advisory opinions made after the date which is 90 days after August 5, 1997, and before the close of the period described in section 1320a–7d(b)(6) of this title.

(h) Definitions and special rules

For purposes of this section:

(1) Compensation arrangement; remuneration

(A) The term “compensation arrangement” means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).

(B) The term “remuneration” includes any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.

(C) Remuneration described in this subparagraph is any remuneration consisting of any of the following:

(i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed tests or procedures, or the correction of minor billing errors.

(ii) The provision of items, devices, or supplies that are used solely to—

(I) collect, transport, process, or store specimens for the entity providing the item, device, or supply, or

(II) order or communicate the results of tests or procedures for such entity.

(iii) A payment made by an insurer or a self-insured plan to a physician to satisfy a claim, submitted on a fee for service basis, for the furnishing of health services by that physician to an individual who is covered by a policy with the insurer or by the self-insured plan, if—

(I) the health services are not furnished, and the payment is not made, pursuant to a contract or other arrangement between the insurer or the plan and the physician,

(II) the payment is made to the physician on behalf of the covered individual and would otherwise be made directly to such individual,

(III) the amount of the payment is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account directly or indirectly the volume or value of any referrals, and

(IV) the payment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

(2) Employee

An individual is considered to be “employed by” or an “employee” of an entity if the indi-
vidual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

(3) Fair market value
The term "fair market value" means the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(4) Group practice
(A) Definition of group practice
The term "group practice" means a group of 2 or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association—

(i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel,

(ii) for which substantially all of the services of the physicians who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group,

(iii) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined,

(iv) except as provided in subparagraph (B)(i), in which no physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician,

(v) in which members of the group personally conduct no less than 75 percent of the physician-patient encounters of the group practice, and

(vi) which meets such other standards as the Secretary may impose by regulation.

(B) Special rules
(i) Profits and productivity bonuses
A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.

(ii) Faculty practice plans
In the case of a faculty practice plan associated with a hospital, institution of higher education, or medical school with an approved medical residency training program in which physician members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, subparagraph (A) shall be applied only with respect to the services provided within the faculty practice plan.

(5) Referral; referring physician
(A) Physicians' services
Except as provided in subparagraph (C), in the case of an item or service for which payment may be made under part B of this subchapter, the request by a physician for the item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician, constitutes a "referral" by a "referring physician".

(B) Other items
Except as provided in subparagraph (C), the request or establishment of a plan of care by a physician which includes the provision of the designated health service constitutes a "referral" by a "referring physician".

(C) Clarification respecting certain services integral to a consultation by certain specialists
A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician".

(6) Designated health services
The term "designated health services" means any of the following items or services:

(A) Clinical laboratory services.

(B) Physical therapy services.

(C) Occupational therapy services.

(D) Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.

(E) Radiation therapy services and supplies.

(F) Durable medical equipment and supplies.

(G) Parenteral and enteral nutrients, equipment, and supplies.

(H) Prosthetics, orthotics, and prosthetic devices and supplies.

(I) Home health services.

(J) Outpatient prescription drugs.

(K) Inpatient and outpatient hospital services.

(L) Outpatient speech-language pathology services.
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(7) Specialty hospital

(A) In general

For purposes of this section, except as provided in subparagraph (B), the term "specialty hospital" means a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that is primarily or exclusively engaged in the care and treatment of one of the following categories:

(i) Patients with a cardiac condition.
(ii) Patients with an orthopedic condition.
(iii) Patients receiving a surgical procedure.
(iv) Any other specialized category of services that the Secretary designates as inconsistent with the purpose of permitting physician ownership and investment interests in a hospital under this section.

(B) Exception

For purposes of this section, the term "specialty hospital" does not include any hospital—

(i) determined by the Secretary—

(I) to be in operation before November 18, 2003; or

(II) under development as of such date;

(ii) for which the number of physician investors at any time on or after such date is no greater than the number of such investors as of such date;

(iii) for which the type of categories described in subparagraph (A) at any time on or after such date is no different than the type of such categories as of such date;

(iv) for which any increase in the number of beds occurs only in the facilities on the main campus of the hospital and does not exceed 50 percent of the number of beds in the hospital as of November 18, 2003, or 5 beds, whichever is greater; and

(v) that meets such other requirements as the Secretary may specify.

(i) Requirements for hospitals to qualify for rural provider and hospital exception to ownership or investment prohibition

(1) Requirements described

For purposes of subsection (d)(3)(D), the requirements described in this paragraph for a hospital are as follows:

(A) Provider agreement

The hospital had—

(i) physician ownership or investment on December 31, 2010; and

(ii) a provider agreement under section 1395cc of this title in effect on such date.

(B) Limitation on expansion of facility capacity

Except as provided in paragraph (3), the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after March 23, 2010, is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date.

(C) Preventing conflicts of interest

(i) The hospital submits to the Secretary an annual report containing a detailed description of—

(I) the identity of each physician owner or investor and any other owners or investors of the hospital; and

(II) the nature and extent of all ownership and investment interests in the hospital.

(ii) The hospital has procedures in place to require that any referring physician owner or investor discloses to the patient being referred, by a time that permits the patient to make a meaningful decision regarding the receipt of care, as determined by the Secretary—

(I) the ownership or investment interest, as applicable, of such referring physician in the hospital; and

(II) if applicable, any such ownership or investment interest of the treating physician.

(iii) The hospital does not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(iv) The hospital discloses the fact that the hospital is partially owned or invested in by physicians—

(I) on any public website for the hospital; and

(II) in any public advertising for the hospital.

(D) Ensuring bona fide investment

(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of March 23, 2010.

(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaran-
ted receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

(E) Patient safety

(i) Insofar as the hospital admits a patient and does not have any physician available on the premises to provide services during all hours in which the hospital is providing services to such patient, before admitting the patient—
   (I) the hospital discloses such fact to a patient; and
   (II) following such disclosure, the hospital receives from the patient a signed acknowledgment that the patient understands such fact.

(ii) The hospital has the capacity to—
   (I) provide assessment and initial treatment for patients; and
   (II) refer and transfer patients to hospitals with the capability to treat the needs of the patient involved.

(F) Limitation on application to certain converted facilities

The hospital was not converted from an ambulatory surgical center to a hospital on or after March 23, 2010.

(2) Publication of information reported

The Secretary shall publish, and update on an annual basis, the information submitted by hospitals under paragraph (1)(C)(i) on the public Internet website of the Centers for Medicare & Medicaid Services.

(3) Exception to prohibition on expansion of facility capacity

(A) Process

   (i) Establishment

   The Secretary shall establish and implement a process under which a hospital that is an applicable hospital (as defined in subparagraph (E)) or is a high Medicaid facility described in subparagraph (F) may apply for an exception from the requirement under paragraph (1)(B).

   (ii) Opportunity for community input

   The process under clause (i) shall provide individuals and entities in the community in which the applicable hospital applying for an exception is located with the opportunity to provide input with respect to the application.

   (iii) Timing for implementation

   The Secretary shall implement the process under clause (i) on February 1, 2012.

   (iv) Regulations

   Not later than January 1, 2012, the Secretary shall promulgate regulations to carry out the process under clause (i).

   (B) Frequency

   The process described in subparagraph (A) shall permit an applicable hospital to apply for an exception up to once every 2 years.

   (C) Permitted increase

   (i) In general

   Subject to clause (ii) and subparagraph (D), an applicable hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed above the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital (or, if the applicable hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after the application of the most recent increase under such an exception).

   (ii) 100 percent increase limitation

   The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed under clause (i) to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital.

   (iii) Baseline number of operating rooms, procedure rooms, and beds

   In this paragraph, the term “baseline number of operating rooms, procedure rooms, and beds” means the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of such date but does have such an agreement in effect on December 31, 2010, the effective date of such provider agreement).

   (D) Increase limited to facilities on the main campus of the hospital

   Any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed pursuant to this paragraph may only occur in facilities on the main campus of the applicable hospital.

   (E) Applicable hospital

   In this paragraph, the term “applicable hospital” means a hospital—

   (i) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date of the application under subparagraph (A)) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census;

   (ii) whose annual percent of total inpatient admissions that represent inpatient

   (F) Limitation on application to certain converted facilities

   The hospital was not converted from an ambulatory surgical center to a hospital on or after March 23, 2010.
admissions under the program under subchapter XIX is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;
(ii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;
(iii) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and
(iv) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.

(F) High Medicaid facility described
A high Medicaid facility described in this subparagraph is a hospital that—
(i) is not the sole hospital in a county;
(ii) with respect to each of the 3 most recent years for which data are available, has an annual percent of total inpatient admissions that represent inpatient admissions under subchapter XIX that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and
(iii) meets the conditions described in subparagraph (E)(iii).

(G) Procedure rooms
In this subsection, the term "procedure rooms" includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

(H) Publication of final decisions
Not later than 60 days after receiving a complete application under this paragraph, the Secretary shall publish in the Federal Register the final decision with respect to such application.

(I) Limitation on review
There shall be no administrative or judicial review under section 1395ff of this title, or otherwise of the process under this paragraph (including the establishment of such process).

(4) Collection of ownership and investment information
For purposes of subparagraphs (A)(i) and (D)(i) of paragraph (I), the Secretary shall collect physician ownership and investment information for each hospital.

(5) Physician owner or investor defined
For purposes of this subsection, the term "physician owner or investor" means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

(6) Clarification
Nothing in this subsection shall be construed as preventing the Secretary from revoking a hospital's provider agreement if not in compliance with regulations implementing section 1395cc of this title.


REFERENCES IN TEXT
Section 222(a) of the Social Security Amendments of 1972, referred to in subsec. (b)(3)(C), is section 222(a) of Pub. L. 92-603, Oct. 30, 1972, 86 Stat. 1329, which is set out as a note under section 1396b-1 of this title.
Section 3000(d) of this title, referred to in subsec. (b)(3)(D), was redesignated section 3000-9(e)(3) of this title by Pub. L. 100-517, §7(b), Oct. 21, 1988, 102 Stat. 2580. Part C of this subchapter, referred to in subsec. (b)(3)(E), is classified to section 1395w-21 et seq. of this title.
Section 1395w–104(e)(6) of this title, referred to in subsec. (b)(5), was in the original "section 1860D–3(e)(6)", and was translated as reading "section 1860D–4(e)(6)", meaning section 1860D–4(e)(6) of the Social Security Act, to reflect the probable intent of Congress, because section 1860D–3, which is classified to section 1395w–103 of this title, does not contain a subsec. (e), and section 1860D–4(e)(6) relates to electronic prescription program regulations. The Internal Revenue Code, referred to in subsec. (c)(2) and (h)(2), is classified generally to Title 26, Internal Revenue Code. Part B of this subchapter, referred to in subsec. (b)(5)(A), is classified to section 1395 et seq. of this title.

PRIOR PROVISIONS

AMENDMENTS
2010—Subsec. (b)(2). Pub. L. 111-148, §6003(a), inserted at end of concluding provisions "Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (b)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain..."
money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.


Pub. L. 101–508, §4207(e)(1)(A), (B), formerly §4027(e)(1)(A), (B), as redesignated by Pub. L. 103–432, §160(d)(4), substituted “in the case of an item or service for which payment may be made under part B of this subchapter, the request by a physician for the item or service,” for “in the case of a clinical laboratory service which under law is required to be provided by (or under the supervision of) a physician, the request by a physician for the service,” in subpar. (A) and struck out “in the case of another clinical laboratory service,” after “subparagraph (C),” in subpar. (B).


CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 109–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title VI, §6001(b), Mar. 23, 2010, 124 Stat. 697, provided that: "The amendment made by this section [amending this section shall apply to services furnished on or after January 1, 2010."

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110–275, set out as a note under section 1395k of this title.

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §524(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–388, provided that: "The amendment made by this section [amending this section shall apply to services furnished on or after the date of the enactment of this Act [Nov. 29, 1999]."

EFFECTIVE DATE OF 1994 AMENDMENT

Section 152(d)(1) of Pub. L. 103–332 provided that: "The amendments made by subsections (a) and (b) [amending this section] shall apply to referrals made on or after January 1, 1995."

EFFECTIVE DATE OF 1993 AMENDMENT

Section 13562(b) of Pub. L. 103–66, as amended by Pub. L. 103–432, title I, §152(c), Oct. 31, 1994, 108 Stat. 4377, provided that:

"(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section [amending this section shall apply to referrals made on or after January 1, 1992.

"(2) EXCEPTIONS.—With respect to referrals made for clinical laboratory services on or before December 31, 1994—

(A) the second sentence of subsection (a)(2), and subsections (b)(2)(B) and (d)(2), of section 1877 of the Social Security Act [subsecs. (a)(2), (b)(2)(B), and (d)(2) of this section] (as in effect on the day before the date of the enactment of this Act [Aug. 10, 1993]) shall apply instead of the corresponding provisions in section 1877 (as amended by this Act);

(B) section 1877(b)(4) of the Social Security Act [subsec. (b)(4) of this section] (as in effect on the day before the date of the enactment of this Act) shall apply; and

(C) the requirements of section 1877(c)(2) of the Social Security Act [subsec. (c)(2) of this section] (as amended by this Act) shall not apply to any securities of a corporation that meets the requirements of section 1877(c)(2) of the Social Security Act (as in effect on the day before the date of the enactment of this Act);"

"(D) section 1877(e)(3) of the Social Security Act [subsec. (e)(3) of this section] (as amended by this Act) shall apply, except that it shall not apply to any arrangement that meets the requirements of section 1877(e)(2) or subsection (e)(3) of section 1877 of the Social Security Act (as in effect on the day before the date of the enactment of this Act);

"(E) the requirements of clauses (iv) and (v) of section 1877(h)(4)(A), and of clause (i) of section 1877(h)(4)(B), of the Social Security Act [subsec. (h)(4)(A)(iv), (v), (B)(1) of this section] (as amended by this Act) shall not apply; and

"(F) section 1877(h)(4)(B) of the Social Security Act [subsec. (h)(4)(B) of this section] (as in effect on the day before the date of the enactment of this Act) shall apply instead of section 1877(h)(4)(A)(i) of such Act (as amended by this Act)."

"[Section 152(d)(2) of Pub. L. 103–432 provided that: "The amendment made by this subsection [amending this section and provisions set out below] shall be effective as if included in the enactment of OBRA–1993 [Pub. L. 103–66]."]"

EFFECTIVE DATE OF 1990 AMENDMENT


EFFECTIVE DATE

Section 6204(c) of Pub. L. 101–239 provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [enacting this section and amending section 1396v of this title] shall become effective with respect to referrals made on or after January 1, 1992.

"(2) The reporting requirement of section 1877(f) of the Social Security Act [subsec. (f) of this section] shall take effect on October 1, 1990."

DEADLINE FOR CERTAIN REGULATIONS


ENFORCEMENT


"(1) ENSURING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to ensure compliance with the requirements described in subsection (i)(1) of section 1877 of the Social Security Act [42 U.S.C. 1395nn(i)(1)], as added by subsection (i)(1), beginning on the date such requirements first apply. Such policies and procedures may include unannounced site reviews of hospitals.

"(2) AUDITS.—Beginning not later than May 1, 2012, the Secretary of Health and Human Services shall conduct audits to determine if hospitals violate the requirements referred to in paragraph (1)."
MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL
Pub. L. 111–148, title VI, § 6049, Mar. 23, 2010, 124 Stat. 772, provided that:

(a) DEVELOPMENT OF SELF-REFERRAL DISCLOSURE PROTOCOL—

“(1) IN GENERAL.—The Secretary of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, shall establish, not later than 6 months after the date of the enactment of this Act (Mar. 23, 2010), a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn) pursuant to a self-referral disclosure protocol (in this section referred to as an ‘SRDP’). The SRDP shall include direction to health care providers of services and suppliers on—

“(A) a specific person, official, or office to whom such disclosures shall be made; and

“(B) instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.

(b) PUBLICATION ON INTERNET WEBSITE OF SRDP INFORMATION.—The Secretary of Health and Human Services shall post information on the public Internet website of the Centers for Medicare & Medicaid Services to inform relevant stakeholders of how to disclose actual or potential violations pursuant to an SRDP.

(c) RELATION TO ADVISORY OPINIONS.—The SRDP shall be separate from the advisory opinion process set forth in regulations implementing section 1877(g) of the Social Security Act (42 U.S.C. 1395nn(g)).

(d) REDUCTION IN AMOUNT OWED.—The Secretary of Health and Human Services is authorized to reduce the amount due and owing for all violations under section 1877 of the Social Security Act (42 U.S.C. 1395nn) to an amount less than that specified in subsection (g) of such section. In establishing such amount for a violation, the Secretary may consider the following factors:

“(1) the nature and extent of the improper or illegal practice;

“(2) the timeliness of such self-disclosure;

“(3) the cooperation in providing additional information related to the disclosure;

“(4) such other factors as the Secretary considers appropriate.

(e) REPORT.—Not later than 18 months after the date on which the SRDP protocol is established under subsection (a)(1), the Secretary shall submit to Congress a report on the implementation of this section. Such report shall include—

“(1) the number of health care providers of services and suppliers making disclosures pursuant to the SRDP;

“(2) the amounts collected pursuant to the SRDP;

“(3) the types of violations reported under the SRDP; and

“(4) such other information as may be necessary to evaluate the impact of this section.”

APPLICATION OF EXCEPTION FOR HOSPITALS UNDER DEVELOPMENT
Pub. L. 110–173, title V, § 507(b), Dec. 8, 2009, 123 Stat. 729, provided that:

“(1) Establishment.—The Medicare Payment Advisory Commission, in consultation with the Comptroller General of the United States, shall conduct a study to determine—

“(A) any differences in the costs of health care services furnished to patients by physician-owned specialty hospitals and the costs of such services furnished by local full-service community hospitals within specific diagnosis-related groups;

“(B) the extent to which specialty hospitals, relative to local full-service community hospitals, treat patients in certain diagnosis-related groups within a category, such as cardiology, and an analysis of the selection;

“(C) the financial impact of physician-owned specialty hospitals on local full-service community hospitals;

“(D) how the current diagnosis-related group system should be updated to better reflect the cost of delivering care in a hospital setting; and

“(E) the proportions of payments received, by type of payer, between the specialty hospitals and local full-service community hospitals.

“(2) HHS STUDY.—The Secretary of Health and Human Services shall conduct a study of a representative sample of specialty hospitals—

“(A) to determine the percentage of patients admitted to physician-owned specialty hospitals who are referred by physicians with an ownership interest in the specialty hospitals;

“(B) to determine the referral patterns of physician owners, including the percentage of patients they referred to physician-owned specialty hospitals and the percentage of patients they referred to local full-service community hospitals for the same condition;

“(C) to compare the quality of care furnished in physician-owned specialty hospitals and in local full-service community hospitals for similar conditions and patient satisfaction with such care; and

“(D) to assess the differences in uncompensated care, as defined by the Secretary, between the specialty hospital and local full-service community hospitals, and the relative value of any tax exemption available to such hospitals.

“(3) Revise.—Not later than 15 months after the date of the enactment of this Act (Dec. 8, 2009), the Commission and the Secretary, respectively, shall each submit to Congress a report on the studies conducted under paragraphs (1) and (2), respectively, and shall include any recommendations for legislation or administrative changes.”

GAO STUDY OF OWNERSHIP BY REFERRING PHYSICIANS
Section 620(e) of Pub. L. 101–239 directed Comptroller General to conduct a study of ownership of hospitals and other providers of Medicare services by referring physicians and, by not later than Feb. 1, 1991, report to Congress on results of such study, prior to repeal by Pub. L. 102–383.

STATISTICAL SUMMARY OF COMPARATIVE UTILIZATION

§ 1395oo. Provider Reimbursement Review Board

(a) Establishment

Any provider of services which has filed a required cost report within the time specified in
regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the "Board") which shall be established by the Secretary in accordance with subsection (b) of this section and (except as provided in subsection (g)(2) of this section) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1395ww of this title and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board if—

(1) such provider—
   (A)(i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report, or
   (B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report,
   (C) has not received such final determination from such intermediary on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary’s final determination under paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(i), 180 days after notice of the Secretary’s final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

(b) Appeals by groups

The provisions of subsection (a) of this section shall apply to any group of providers of services if each provider of services in such group would, upon the filing of an appeal (but without regard to the $10,000 limitation), be entitled to such a hearing, but only if the matters in controversy involve a common question of fact or interpretation of law or regulations and the amount in controversy is, in the aggregate, $50,000 or more.

(e) Right to counsel; rules of evidence

At such hearing, the provider of services shall have the right to be represented by counsel, to introduce evidence, and to examine and cross-examine witnesses. Evidence may be received at any such hearing even though inadmissible under rules of evidence applicable to court procedure.

(2) the amount in controversy is $10,000 or more.

(3) such provider files a request for a hearing within 180 days after notice of the intermediary’s final determination under paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(i), 180 days after notice of the Secretary’s final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board’s decision, reverses, affirms, or modifies the Board’s decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to

(d) Decisions of Board

A decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the intermediary and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole. The Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination.

(e) Rules and regulations

The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this subchapter or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this section. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 405 of this title with respect to subpoenas shall apply to the Board to the same extent as they apply to the Secretary with respect to subchapter II of this chapter.

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board’s decision, reverses, affirms, or modifies the Board’s decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to

(d) Decisions of Board

A decision by the Board shall be based upon the record made at such hearing, which shall include the evidence considered by the intermediary and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole. The Board shall have the power to affirm, modify, or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report (including revisions adverse to the provider of services) even though such matters were not considered by the intermediary in making such final determination.

(e) Rules and regulations

The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this subchapter or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this section. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 405 of this title with respect to subpoenas shall apply to the Board to the same extent as they apply to the Secretary with respect to subchapter II of this chapter.

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board’s decision, reverses, affirms, or modifies the Board’s decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to
render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to the matter in controversy contained in such request for a hearing. Such action shall be brought in the district court of the United States for the judicial district in which the provider is located (or, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia and shall be tried pursuant to the applicable provisions under chapter 7 of title 5 notwithstanding any other provisions in section 405 of this title. Any appeal to the Board or action for judicial review by providers which are under common ownership or control or which have obtained a hearing under subsection (b) of this section must be brought by such providers as a group with respect to any matter involving an issue common to such providers.

(2) Where a provider seeks judicial review pursuant to paragraph (1), the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 180-day period as determined pursuant to subsection (a)(3) of this section and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund for the month in which the civil action authorized under paragraph (1) is commenced, to be awarded by the reviewing court in favor of the prevailing party.

(3) No interest awarded pursuant to paragraph (2) shall be deemed income or cost for the purposes of determining reimbursement due providers under this chapter.

(g) Certain findings not reviewable

(1) The finding of a fiscal intermediary that no payment may be made under this subchapter for any expenses incurred for items or services furnished to an individual because such items or services are listed in section 1395y of this title shall not be reviewed by the Board, or by any court pursuant to an action brought under subsection (f) of this section.

(2) The determinations and other decisions described in section 1395ww(d)(7) of this title shall not be reviewed by the Board or by any court pursuant to an action brought under subsection (f) of this section or otherwise.

(h) Composition and compensation

The Board shall be composed of five members appointed by the Secretary without regard to the provisions of title 5 governing appointments in the competitive services. Two of such members shall be representative of providers of services. All of the members of the Board shall be persons knowledgeable in the field of payment of providers of services, and at least one of them shall be a certified public accountant. Members of the Board shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding the rate specified (at the time the service involved is rendered by such member) for grade GS–18 in section 5332 of title 5. The term of office shall be three years, except that the Secretary shall appoint the initial members of the Board for shorter terms to the extent necessary to permit staggered terms of office.

(i) Technical and clerical assistance

The Board is authorized to engage such technical and clerical assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(j) “Provider of services” defined

In this section, the term “provider of services” includes a rural health clinic and a Federally qualified health center.


AMENDMENTS

1993—Subsec. (f)(2). Pub. L. 103–66 substituted “the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund for the month in which the ratification of the amendment to the Constitution was submitted to the states in the manner prescribed by Article V of the Constitution” for “the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund for the month in which the rate of return on equity capital established by regulation pursuant to section 1395f(v)(1)(B) of this title and in effect at the time”.


Subsec. (e). Pub. L. 98–369, § 2354(b)(40), substituted “and (e)” for “(e), (d), and (f)”.

Subsec. (f)(1). Pub. L. 98–369, § 2351(a)(1), substituted “notification of such determination is received” for “such determination is rendered” in third sentence.


Subsec. (e). Pub. L. 98–369, § 2354(b)(40), substituted “and (e)” for “(e), (d), and (f)”.

Subsec. (f)(1). Pub. L. 98–369, § 2351(a)(1), inserted “‘notification of such determination is received’” for “‘such determination is rendered’ in third sentence.


Subsec. (h). Pub. L. 98–369, § 2354(b)(40), substituted “‘inadmissable’” for “‘inadmissible’”.

Subsec. (i). Pub. L. 98–369, § 2354(b)(40), substituted “‘inadmissable’” for “‘inadmissible’”.

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The Board is authorized to engage such technical and clerical assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

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Subsec. (e). Pub. L. 98–369, § 2354(b)(40), substituted “and (e)” for “(e), (d), and (f)”.

Subsec. (f)(1). Pub. L. 98–369, § 2351(a)(1), inserted “‘notification of such determination is received’” for “‘such determination is rendered’ in third sentence.


Subsec. (h). Pub. L. 98–369, § 2354(b)(40), substituted “‘inadmissable’” for “‘inadmissible’”.

Subsec. (i). Pub. L. 98–369, § 2354(b)(40), substituted “‘inadmissable’” for “‘inadmissible’”.
question of law or regulations relevant to matters in controversy whenever Board determined that it was without authority to decide such matters in controversy.

1974—Subsec. (f). Pub. L. 93–484 redesignated existing provisions as par. (1), inserted provisions authorizing judicial review for providers of final decisions of Board and judicial review of any affiance by Secretary, and added pars. (2) and (3).

**Effective Date of 1993 Amendment**


**Effective Date of 1990 Amendment**


Amendment by section 4161(b)(4) of Pub. L. 101–508 applicable to cost reports for periods beginning on or after Oct. 1, 1991, see section 4161(b)(5) of Pub. L. 101–508, set out as a note under section 1395x of this title.

**Effective Date of 1984 Amendment**

Section 2351(a)(2) of Pub. L. 98–369 provided that: "The amendment made by paragraph (1) [amending this section] shall be effective with respect to any civil action commenced on or after the date of the enactment of this Act [July 18, 1984]."

Section 2351(b)(2) of Pub. L. 98–369 provided that: "The amendment made by paragraph (1) [amending this section] shall be effective with respect to any appeal or action brought on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2354(b)(39), (40) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1983 Amendment**

Amendment by 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 1395w of this title. See, also, section 2351(c) of Pub. L. 98–369, set out as a note below.

**Effective Date of 1974 Amendment**

Section 3(b) of Pub. L. 93–484 provided that: "The amendment made by subsection (a) [amending this section] shall be applicable to cost reports of providers of services for accounting periods ending on or after June 30, 1973."

**Effective Date**

Section 243(c) of Pub. L. 92–693 provided that: "The amendments made by this section [enacting this section and amending section 1395h of this title] shall apply with respect to cost reports of providers of services, as defined in title XVIII of the Social Security Act [this subchapter], for accounting periods ending on or after June 30, 1973."

**References in Other Laws to GS–16, 17, or 18 Pay Rates**

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 (title I, §10(c)(1)) of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

**Review of Provider Reimbursement Review Board Decisions**

Section 2351(c) of Pub. L. 98–369 provided that: "Notwithstanding section 604 of the Social Security Amendments of 1983 (Public Law 98–21) [set out as an Effective Date of 1983 Amendments note under section 1395w of this title]—

"(1) the amendments made by section 602(h)(2)(A) of that Act [amending this section] shall be effective with respect to any appeal or action brought on or after April 20, 1983; and

"(2) the amendments made by section 602(h)(2)(B) of that Act [amending this section] shall be effective with respect to any appeal or action brought on or after the date of the enactment of this Act (July 18, 1984)."

§ 1395pp. Limitation on liability where claims are disallowed

(a) Conditions prerequisite to payment for items and services notwithstanding determination of disallowance

Where—

(1) a determination is made that, by reason of section 1395y(a)(1) or (9) of this title or by reason of a coverage denial described in subsection (g) of this section, payment may not be made under part A or part B of this subchapter for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1395a(b)(3)(B)(ii) of this title, and

(2) both such individual and such provider of services or such other person, as the case may be, did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services under such part A or part B of this subchapter, then to the extent permitted by this subchapter, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this subchapter), as though section 1395y(a)(1) and section 1395y(a)(9) of this title did not apply and as though the coverage denial described in subsection (g) of this section had not occurred. In each such case the Secretary shall notify both such individual and such provider of services or such other person, as the case may be, of the conditions under which payment for such items or services was made and in the case of comparable situations arising thereafter with respect to such individual or such provider or such other person, each shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made by reason of a coverage denial described in subsection (g) of this section shall be deemed to have knowledge that payment cannot be made.
for such items or services if the claim relating to such items or services involves a case, provider or other person furnishing services, procedure, or test, with respect to which such provider or other person has been notified by the Secretary (including notification by a utilization and quality control peer review organization) that a pattern of inappropriate utilization has occurred in the past, and such provider or other person has been allowed a reasonable time to correct such inappropriate utilization.

(b) Knowledge of person or provider that payment could not be made; indemnification of individual

In any case in which the provisions of paragraphs (1) and (2) of subsection (a) of this section are met, except that such provider or such other person, as the case may be, knew, or could be expected to know, that payment for such services or items could not be made under such part A or part B of this subchapter, then the Secretary shall, upon proper application filed within such time as may be prescribed in regulations, indemnify the individual (referred to in such paragraphs) for any payments received from such individual by such provider or such other person, as the case may be, for such items or services. Any payments made by the Secretary as indemnification shall be deemed to have been made to such provider or such other person, as the case may be, and shall be treated as overpayments, recoverable from such provider or such other person, as the case may be, under applicable provisions of law. In each such case the Secretary shall notify such individual of the conditions under which indemnification is made and in the case of comparable situations arising thereafter with respect to such individual, he shall, by reason of such notice (or similar notices provided before the enactment of this section), be deemed to have knowledge that payment cannot be made for such items or services. No item or service for which an individual is indemnified under this subsection shall be taken into account in applying any limitation on the amount of items and services for which payment may be made to or on behalf of the individual under this subchapter.

(c) Knowledge of both provider and individual to whom items or services were furnished that payment could not be made

No payments shall be made under this subchapter in any cases in which the provisions of paragraph (1) of subsection (a) of this section are met, but both the individual to whom the items or services were furnished and the provider of service or other person, as the case may be, who furnished the items or services knew, or could reasonably have been expected to know, that payment could not be made for items or services under part A or part B of this subchapter by reason of section 1395y(a)(1) or (a)(2) of such title or by reason of a coverage denial described in subsection (g) of this section.

(d) Exercise of rights

In any case arising under subsection (b) of this section (but without regard to whether payments have been made by the individual to the provider or other person) or subsection (c) of this section, the provider or other person shall have the same rights that an individual has under sections 1395ff(b) and 1395u(b)(3)(C) of this title (as may be applicable) when the amount of benefit or payments is in controversy, except that such rights may, under prescribed regulations, be exercised by such provider or other person only after the Secretary determines that the individual will not exercise such rights under such sections.

(e) Payment where beneficiary not at fault

Where payment for inpatient hospital services or extended care services may not be made under part A of this subchapter on behalf of an individual entitled to benefits under such part solely because of an unintentional, inadvertent, or erroneous action with respect to the transfer of such individual from a hospital or skilled nursing facility that meets the requirements of section 1395x(e) or (j) of this title by such a provider of services acting in good faith in accordance with the advice of a utilization review committee, quality control and peer review organization, or fiscal intermediary, or on the basis of a clearly erroneous administrative decision by a provider of services, the Secretary shall take such action with respect to the payment of such benefits as he determines may be necessary to correct the effects of such unintentional, inadvertent, or erroneous action.

(f) Presumption with respect to coverage denial; rebuttal; requirements; “fiscal intermediary” defined

(1) A home health agency which meets the applicable requirements of paragraphs (3) and (4) shall be presumed to meet the requirement of subsection (a)(2) of this section.

(2) The presumption of paragraph (1) with respect to specific services may be rebutted by actual or imputed knowledge of the facts described in subsection (a)(2) of this section, including any of the following:

(A) Notice by the fiscal intermediary of the fact that payment may not be made under this subchapter with respect to the services.

(B) It is clear and obvious that the provider should have known at the time the services were furnished that they were excluded from coverage.

(3) The requirements of this paragraph are as follows:

(A) The agency complies with requirements of the Secretary under this subchapter respecting timely submittal of bills for payment and medical documentation.

(B) The agency program has reasonable procedures to notify promptly each patient (and the patient’s physician) where it is determined that a patient is being or will be furnished items or services which are excluded from coverage under this subchapter.

(4)(A) The requirement of this paragraph is that, on the basis of bills submitted by a home health agency during the previous quarter, the rate of denial of bills for the agency of a coverage denial described in subsection (g) of this section does not exceed 2.5 percent, computed based on visits for home health services billed.
(B) For purposes of determining the rate of denial of bills for a home health agency under subparagraph (A), a bill shall not be considered to be denied until the expiration of the 60-day period that begins on the date such bill is denied by the fiscal intermediary, or, with respect to such a denial for which the agency requests reconsideration, until the fiscal intermediary issues a decision denying payment for such bill.

(5) In this subsection, the term "fiscal intermediary" means, with respect to a home health agency, an agency or organization with which an agreement under section 1395h of this title with respect to the agency.

(6) The Secretary shall monitor the proportion of denied bills submitted by home health agencies for which reconsideration is requested, and shall notify Congress if the proportion of denials reversed upon reconsideration increases significantly.

(g) Coverage denial defined

The coverage denial described in this subsection is—

(1) with respect to the provision of home health services to an individual, a failure to meet the requirements of section 1395(a)(2)(C) of this title or section 1395m(a)(2)(A) of this title in that the individual—

(A) is or was not confined to his home, or

(B) does or did not need skilled nursing care on an intermittent basis; and

(2) with respect to the provision of hospice care to an individual, a determination that the individual is not terminally ill.

(h) Supplier responsibility for items furnished on assignment basis

If a supplier of medical equipment and supplies (as defined in section 1395m(j)(5) of this title) furnishes an item or service to a beneficiary for which no payment may be made by reason of section 1395m(j)(1) of this title;

(1) furnishes an item or service to a beneficiary for which payment is denied in advance under section 1395m(a)(15) of this title; or

(3) furnishes an item or service to a beneficiary for which no payment may be made by reason of section 1395m(a)(17)(B) of this title, any expenses incurred for items and services furnished to an individual by such a supplier on an assignment-related basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of section 1395m(a)(18) of this title shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such section.


REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in text, are classified to sections 1385c et seq. and 1385 et seq., respectively, of this title.

AMENDMENTS

1997—Subsec. (g). Pub. L. 105-33 substituted "subsection is—" for "subsection is", redesignated text as par. (1) and former pars. (1) and (2) as subpars. (A) and (B), respectively, of par. (1), realigned margins, substituted "and" for period at end, and added par. (2).


1989—Subsec. (f)(1). Pub. L. 101-239, §6214(a)(1), struck out "with respect to any coverage denial described in subsection (g) of this section" before period at end.

Subsec. (f)(4). Pub. L. 101-239, §6214(a)(2), designated existing provisions as subpar. (A) and added subpar. (B).


1987—Subsec. (b). Pub. L. 100-203 struck out "subject to the deductible and coinsurance provisions of this subchapter", after "(referred to in such paragraph)" and inserted at end "No item or service for which an individual is indemnified under this subchapter shall be taken into account in applying any limitation on the amount of items and services for which payment may be made to or on behalf of the individual under this subchapter."

1986—Subsec. (a). Pub. L. 99-509, §9305(g)(1)(A)-(C), inserted in par. (1) "or by reason of a coverage denial described in subsection (g) of this section", and in concluding provisions inserted "and as though the coverage denial described in subsection (g) of this section had not occurred" and "or by reason of a coverage denial described in subsection (g) of this section".

Subsec. (c). Pub. L. 99-509, §9305(g)(1)(D), inserted "or by reason of a coverage denial described in subsection (g) of this section".

Subsec. (d). Pub. L. 99-509, §9314(a)(3), substituted "sections 1395f(b) and 1395u(b)(3)(C) of this title (as may be applicable)" for "section 1395f(b) of this title (when the determination is under part A) or section 1395u(b)(3)(C) of this title (when the determination is under part B)".

Subsecs. (f), (g). Pub. L. 99-509, §9305(g)(1)(E), added subsecs. (f) and (g).

1982—Subsec. (a). Pub. L. 97-248, §145, inserted provisions relating to imputing knowledge to provider or other person furnishing items or services for which payment may not be made that payment may not be made if the provider or other person has been notified that a pattern of inappropriate utilization has occurred in the past and there has been a reasonable time for correction of such utilization.

Subsec. (e). Pub. L. 97-248, §146(e), substituted "quality control and peer review organization" for "professional standards review organization".


EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by 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.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-432 applicable to items or services furnished on or after Jan. 1, 1995, see section 133(c) of Pub. L. 103-432, set out as a note under section 1395m of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6214(c) of Pub. L. 101-239 provided that: "The amendments made by subsection (a) [amending this
section] shall apply to determinations for quarters beginning on or after the date of the enactment of this Act (Dec. 19, 1989)."

**Effective Date of 1987 Amendment**

Amendment by Pub. L. 100–203 applicable to services furnished on or after Jan. 1, 1988, see section 4096(d) of Pub. L. 100–203, set out as a note under section 1320c–3 of this title.

**Effective Date of 1986 Amendment**


Amendment by section 9341(b) of Pub. L. 99–509 applicable to items and services furnished on or after Jan. 1, 1987, see section 9341(b) of Pub. L. 99–509, set out as a note under section 1395ff of this title.

**Effective Date of 1982 Amendment**

Amendment by Pub. L. 97–248 effective with respect to contracts entered into on or renewed on or after Sept. 3, 1982, see section 149 of Pub. L. 97–248, set out as an Effective Date note under section 1320c of this title.

**Effective Date of 1980 Amendment**

Section 956(b) of Pub. L. 96–499 provided that: "The amendment made by subsection (a) [amending this section] shall take effect January 1, 1981."

**Reports to Congress on Denials of Bills for Payment**

Section 9305(g)(2) of Pub. L. 99–509 directed Secretary of Health and Human Services to report to Congress annually in March of 1987 and 1988 information on frequency and distribution (by type of provider) of denials of bills for payment under this subchapter for extended care services, home health services, and hospice care, by reason of section 1395(a)(1) or (9) of this title, and coverage denials described in subsec. (g) of this section, and such other information as appropriate to evaluate the appropriateness of any percentage standards established for the granting of favorable presumptions with respect to such denials.

§ 1395qq. Indian Health Service Facilities

(a) Eligibility for payments; conditions and requirements

A hospital or skilled nursing facility of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 1603 of title 25), shall be eligible for payments under this subchapter, notwithstanding sections 1395f(c) and 1395m(d) of this title, if and for so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals or skilled nursing facilities (as the case may be) under this subchapter.

(b) Eligibility based on submission of plan to achieve compliance with conditions and requirements; twelve-month period

Notwithstanding subsection (a) of this section, a hospital or skilled nursing facility of the Indian Health Service which does not meet all of the conditions and requirements of this subchapter which are applicable generally to hospitals or skilled nursing facilities (as the case may be), but which submits to the Secretary within six months after September 30, 1976, an acceptable plan for achieving compliance with
such conditions and requirements, shall be
deemed to meet such conditions and require-
ments (and to be eligible for payments under
this subchapter), without regard to the extent of
its actual compliance with such conditions and
requirements, during the first 12 months after
the month in which such plan is submitted.
(c) Payments into special fund for improve-
ments to achieve compliance with conditions and
requirements; certification of compliance by
Secretary
Notwithstanding any other provision of this
subchapter, payments to which any hospital or
skilled nursing facility of the Indian Health
Service is entitled by reason of this section shall
be placed in a special fund to be held by the Sec-
retary and used by him (to such extent or in
such amounts as are provided in appropriation
Acts) exclusively for the purpose of making any
improvements in the hospitals and skilled nurs-
ing facilities of such Service which may be nec-
essary to achieve compliance with the applica-
ble conditions and requirements of this sub-
chapter. The preceding sentence shall cease to
apply when the Secretary determines and cer-
tifies that substantially all of the hospitals and
skilled nursing facilities of such Service in the
United States are in compliance with such con-
ditions and requirements.
(d) Report by Secretary; status of facilities in
complying with conditions and requirements
The annual report of the Secretary which is
required by section 1671 of title 25 shall include
(along with the matters specified in section 1643
of title 25) a detailed statement of the status of
the hospitals and skilled nursing facilities of the
Service or tribe (whether provider-based or freest-
anding) that is operated by the Indian Health
Service or by an Indian tribe or tribal organization (as de-
defined for purposes of subsection (a) of this sec-
tion) for services described in paragraph (2) (and
for items and services furnished on or after Jan-
uary 1, 2005, all items and services for which
payment may be made under part B of this sub-
chapter) furnished in or at the direction of the
hospitals or clinic under the same situations,
terms, and conditions as would apply if the ser-
dices were furnished in or at the direction of such
a hospital or clinic that was not operated by
such Service, tribe, or organization.
(B) Payment shall not be made for services
under subparagraph (A) to the extent that pay-
ment is otherwise made for such services under
this subchapter.
(2) The services described in this paragraph are
the following:
(A) Services for which payment is made
under section 1395w–4 of this title.
(B) Services furnished by a practitioner
described in section 1395ub(b)(18)(C) of this title
for which payment under part B of this sub-
chapter is made under a fee schedule.
(C) Services furnished by a physical ther-
papist or occupational therapist as described in
section 1395x(p) of this title for which payment
under part B of this subchapter is made under
a fee schedule.
(3) Subsection (c) of this section shall not
apply to payments made under this subsection.
(f) Cross reference
For provisions relating to the authority of cer-
tain Indian tribes, tribal organizations, and
Alaska Native health organizations to elect to
directly bill for, and receive payment for, health
care services provided by a hospital or clinic of
such tribes or organizations and for which pay-
ment may be made under this subchapter, see
section 1645 of title 25.1
1 See References in Text note below.
to reflect renumbering of corresponding section of original act.

Effective Date of 2010 Amendment

Pub. L. 111–148, title II, §2062(b), Mar. 23, 2010, 124 Stat. 333, provided that: ‘‘The amendments made by this section [amending this section] shall apply to items or services furnished on or after January 1, 2010.’’

Effective Date of 2000 Amendment

Amendment by Pub. L. 106–554 applicable to services furnished on or after July 1, 2001, see section 1(a)(6) [title IV, §432(c)] of Title 25, Indians.

Medicare Payments Not Considered in Determining Appropriations for Indian Health Care

Pub. L. 94–437, title IV, §401(c), Sept. 30, 1976, 90 Stat. 1409, provided that any payments received for services provided to beneficiaries under this section were not to be considered in determining appropriations for health care and services to Indians, prior to the general amendment of section 401 of Pub. L. 94–437 by Pub. L. 102–573, title IV, §401(a), Oct. 29, 1992, 106 Stat. 4565. Similar provisions are contained in section 401(a) of Pub. L. 94–437, which is classified to section 1641(a) of Title 25, Indians.

Preference in Services for Indians With Medicare Coverage Not Authorized

Pub. L. 94–437, title IV, §401(d), Sept. 30, 1976, 90 Stat. 1409, provided that nothing in this section authorized the Secretary to provide services to an Indian beneficiary with coverage under this subchapter in preference to an Indian beneficiary without such coverage, prior to the general amendment of section 401 of Pub. L. 94–437 by Pub. L. 102–573, title IV, §401(a), Oct. 29, 1992, 106 Stat. 4565. Similar provisions are contained in section 401(b) of Pub. L. 94–437, which is classified to section 1641(b) of Title 25, Indians.

§1395rr. End stage renal disease program

(a) Type, duration, and scope of benefits

The benefits provided by parts A and B of this subchapter shall include benefits for individuals who have been determined to have end stage renal disease as provided in section 426–1 of this title, and benefits for kidney donors as provided in subsection (d) of this section. Notwithstanding any other provision of this subchapter, the type, duration, and scope of the benefit provided by parts A and B of this subchapter with respect to individuals who have been determined to have end stage renal disease and who are entitled to such benefits without regard to section 426–1 of this title shall in no case be less than the type, duration, and scope of the benefits so provided for individuals entitled to such benefits solely by reason of that section.

(b) Payments with respect to services; dialysis; regulations; physicians’ services; target reimbursement rates; home dialysis supplies and equipment; self-care home dialysis support services; self-care dialysis units; hepatitis B vaccine

(1) Payments under this subchapter with respect to services, in addition to services for which payment would otherwise be made under this subchapter, furnished to individuals who have been determined to have end stage renal disease shall include (A) payments on behalf of such individuals to providers of services and renal dialysis facilities which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies (including self-dialysis services, such as a self-care dialysis unit maintained by the provider or facility), transplantation services, self-care home dialysis support services which are furnished by the provider or facility, and routine professional services performed by a physician during a maintenance dialysis episode if payments for his other professional services furnished to an individual who has end stage renal disease are made on the basis specified in paragraph (3)(A) of this subsection, (B) payments to or on behalf of such individuals for home dialysis supplies and equipment, and (C) payments to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for self-administered erythropoietin as described in section 1395x(s)(2)(P) of this title if the Secretary finds that the patient receiving such drug from such a supplier can safely and effectively administer the drug (in accordance with the applicable methods and standards established by the Secretary pursuant to such section). The requirements prescribed by the Secretary under subparagraph (A) shall include requirements for a minimum utilization rate for transplantations.

(2)(A) With respect to payments for dialysis services furnished by providers of services and renal dialysis facilities to individuals determined to have end stage renal disease for which payments may be made under part B of this subchapter, such payments (unless otherwise provided in this section) shall be equal to 80 percent of the amounts determined in accordance with subparagraph (B); and with respect to payments for services for which payments may be made under part A of this subchapter, the amounts of such payments (which amounts shall not exceed, in respect to costs in procuring organs attributable to payments made to an organ procurement agency or histocompatibility laboratory, the costs incurred by that agency or laboratory) shall be determined in accordance with section 1395v(v) of this title or section 1395ww of this title (if applicable). Payments shall be made to a renal dialysis facility only if it agrees to accept such payments as payment in full for covered services, except for payment by the individual of 20 percent of the estimated amounts for such services calculated on the basis established by the Secretary under subparagraph (B) and the deductible amount imposed by section 1395(b) of this title.

(B) The Secretary shall prescribe in regulations any methods and procedures to (i) determine the costs incurred by providers of services and renal dialysis facilities in furnishing covered services to individuals determined to have end stage renal disease, and (ii) determine, on a cost-related basis or other economical and equitable basis (including any basis authorized under section 1395x(v) of this title) and consistent with any regulations promulgated under paragraph (7), the amounts of payments to be

1 See References in Text note below.
made for part B services furnished by such providers and facilities to such individuals.

(C) Such regulations, in the case of services furnished by proprietary providers and facilities (other than hospital outpatient departments) may, if the Secretary finds it feasible and appropriate, provision for recognition of a reasonable rate of return on equity capital, providing such rate of return does not exceed the rate of return stipulated in section 1395x(v)(1)(B) of this title.

(D) For purposes of section 1395oo of this title, a renal dialysis facility shall be treated as a provider of services.

(3) With respect to payments for physicians’ services furnished to individuals determined to have end stage renal disease, the Secretary shall pay 80 percent of the amounts calculated for such services—

(A) on a reasonable charge basis (but may, in such case, make payment on the basis of the prevailing charges of other physicians for comparable services or, for services furnished on or after January 1, 1992, on the basis described in section 1395w-4 of this title) except that payment may not be made under this subparagraph for routine services furnished during a maintenance dialysis episode, or

(B) on a comprehensive monthly fee or other basis (which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis) for an aggregate of services provided over a period of time (as defined in regulations).

(4) (A) Pursuant to agreements with approved providers of services and renal dialysis facilities, the Secretary may make payments to such providers and facilities for the cost of home dialysis supplies and equipment and self-care home dialysis support services furnished to patients whose self-care home dialysis is under the direct supervision of such provider or facility, on the basis of a target reimbursement rate (as defined in paragraph (6)) or on the basis of a method established under paragraph (7).

(B) The Secretary shall make payments to a supplier of home dialysis supplies and equipment furnished to a patient whose self-care home dialysis is not under the direct supervision of an approved provider of services or renal dialysis facility only in accordance with a written agreement under which—

(i) the patient certifies that the supplier is the sole provider of such supplies and equipment to the patient,

(ii) the supplier agrees to receive payment for the cost of such supplies and equipment only on an assignment-related basis, and

(iii) the supplier certifies that it has entered into a written agreement with an approved provider of services or renal dialysis facility under which such provider or facility agrees to furnish to such patient all self-care home dialysis support services and all other necessary dialysis services and supplies, including institutional dialysis services and supplies and emergency services.

(5) An agreement under paragraph (4) shall require, in accordance with regulations prescribed by the Secretary, that the provider or facility will—

(A) assume full responsibility for directly obtaining or arranging for the provision of—

(i) such medically necessary dialysis equipment as is prescribed by the attending physician;

(ii) dialysis equipment maintenance and repair services;

(iii) the purchase and delivery of all necessary medical supplies; and

(iv) where necessary, the services of trained home dialysis aides;

(B) perform all such administrative functions and maintain such information and records as the Secretary may require to verify the transactions and arrangements described in subparagraph (A);

(C) submit such cost reports, data, and information as the Secretary may require with respect to the costs incurred for equipment, supplies, and services furnished to the facility’s home dialysis patient population; and

(D) provide for full access for the Secretary to all such records, data, and information as he may require to perform his functions under this section.

(6) The Secretary shall establish, for each calendar year commencing with January 1, 1979, a target reimbursement rate for home dialysis which shall be adjusted for regional variations in the cost of providing home dialysis. In establishing such a rate, the Secretary shall include—

(A) the Secretary’s estimate of the cost of providing medically necessary home dialysis supplies and equipment;

(B) an allowance, in an amount determined by the Secretary, to cover the cost of providing personnel to aid in home dialysis; and

(C) an allowance, in an amount determined by the Secretary, to cover administrative costs and to provide an incentive for the efficient delivery of home dialysis;

but in no event (except as may be provided in regulations under paragraph (7)) shall such target rate exceed 75 percent of the national average payment, adjusted for regional variations, for maintenance dialysis services furnished in approved providers and facilities during the preceding fiscal year. Any such target rate so established shall be utilized, without renegotiation of the rate, throughout the calendar year for which it is established. During the last quarter of each calendar year, the Secretary shall establish a home dialysis target reimbursement rate for the next calendar year based on the most recent data available to the Secretary at the time. In establishing any rate under this paragraph, the Secretary may utilize a competitive-bid procedure, a prenegotiated rate procedure, or any other procedure (including methods established under paragraph (7)) which the Secretary determines is appropriate and feasible in order to carry out this paragraph in an effective and efficient manner.

(7) Subject to paragraph (12), the Secretary shall provide by regulation for a method (or methods) for determining prospectively the amounts of payments to be made for dialysis services furnished by providers of services and renal dialysis facilities to individuals in a facility and to such individuals at home. Such meth-
(c)(2) of this section) for such or-
tive costs incurred in carrying out the respon-
ded in subsection (c)(2) of this para-

(8) For purposes of this subchapter, the term "home dialysis supplies and equipment" means medically necessary supplies and equipment (including supportive equipment) required by an individual suffering from end stage renal disease in connection with renal dialysis carried out in his home (as defined in regulations), including obtaining, installing, and maintaining such equipment.

(9) For purposes of this subchapter, the term "self-care home dialysis support services", to the extent permitted in regulation, means—

(A) periodic monitoring of the patient's home adaptation, including visits by qualified provider or facility personnel (as defined in regulations), so long as this is done in accordance with a plan prepared and periodically reviewed by a professional team (as defined in regulations) including the individual's physician;

(B) installation and maintenance of dialysis equipment;

(C) testing and appropriate treatment of the water; and

(D) such additional supportive services as the Secretary finds appropriate and desirable.

(10) For purposes of this subchapter, the term "self-care dialysis unit" means a renal dialysis facility or a distinct part of such facility or of a provider of services, which has been approved by the Secretary to make self-dialysis services, as defined by the Secretary in regulations, available to individuals who have been trained for self-dialysis. A self-care dialysis unit must, at a minimum, furnish the services, equipment and supplies needed for self-care dialysis, have patient-staff ratios which are appropriate to self-dialysis (allowing for a lesser degree of ongoing medical supervision and assistance of ancillary personnel than is required for full care maintenance dialysis), and meet such other requirements as the Secretary may prescribe with respect to the quality and cost-effectiveness of services.

(A) Hepatitis B vaccine and its administration, when provided to a patient determined to have end stage renal disease, shall not be included as dialysis services for purposes of payment under any prospective payment amount or comprehensive fee established under this section. Payment for such vaccine and its administration shall be made separately in accordance with section 1395rr of this title.

(B) Erythropoietin, when provided to a patient determined to have end stage renal disease, shall not be included as a dialysis service for purposes of payment under any prospective payment amount or comprehensive fee established under this section, and subject to paragraphs (12) and (13) payment for such item shall be made separately—

(i) in the case of erythropoietin provided by a physician, in accordance with section 1395rr of this title; and
shall include—

(I) for erythropoietin provided during 1994, in an amount equal to $10 per thousand units (rounded to the nearest 100 units), and

(II) for erythropoietin provided during a subsequent year, in an amount determined to be appropriate by the Secretary, except that such amount may not exceed the amount determined under this clause for the previous year increased by the percentage increase (if any) in the implicit price deflator for gross national product (as published by the Department of Commerce) for the second quarter of the preceding year over the implicit price deflator for the second quarter of the second preceding year.

(C) The amount payable to a supplier of home dialysis supplies and equipment that is not a provider of services, a renal dialysis facility, or a physician for erythropoietin shall be determined in the same manner as the amount payable to a renal dialysis facility for such item.

(12)(A) Subject to paragraph (14), in lieu of payment under paragraph (7) beginning with services furnished on January 1, 2005, the Secretary shall establish a basic case-mix adjusted payment system for dialysis services furnished by providers of services and renal dialysis facilities in a year to individuals in a facility and to such individuals at home. The case-mix under such system shall be for a limited number of patient characteristics. Under such system, the payment rate for dialysis services furnished on or after January 1, 2009, by providers of services shall be the same as the payment rate (computed without regard to this sentence) for such services furnished by renal dialysis facilities, and in applying the geographic index under subparagraph (D) to providers of services, the labor share shall be based on the labor share otherwise applied for renal dialysis facilities.

(B) The system described in subparagraph (A) shall include—

(i) the services comprising the composite rate established under paragraph (7); and

(ii) the difference between payment amounts under this subchapter for separately billed drugs and biologicals (including erythropoietin) and acquisition costs of such drugs and biologicals, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—

(I) beginning with 2005, for such drugs and biologicals for which a billing code exists prior to January 1, 2004; and

(II) beginning with 2007, for such drugs and biologicals for which a billing code does not exist prior to January 1, 2004, adjusted to 2005, or 2007, respectively, as determined to be appropriate by the Secretary.

(C)(i) In applying subparagraph (B)(ii) for 2005, such payment amounts under this subchapter shall be determined using the methodology specified in paragraph (13)(A)(i).

(ii) For 2006, the Secretary shall provide for an adjustment to the payments under clause (i) to reflect the difference between the payment amounts using the methodology under paragraph (13)(A)(i) and the payment amount determined using the methodology applied by the Secretary under paragraph (13)(A)(iii) of such paragraph, as estimated by the Secretary.

(D) The Secretary shall adjust the payment rates under such system by a geographic index as the Secretary determines to be appropriate. If the Secretary applies a geographic index under this paragraph that differs from the index applied under paragraph (7) the Secretary shall phase-in the application of the index under this paragraph over a multiyear period.

(E)(i) Such system shall be designed to result in the same aggregate amount of expenditures for such services, as estimated by the Secretary, as would have been made for 2005 if this paragraph did not apply.

(ii) The adjustment made under subparagraph (B)(ii)(II) shall be done in a manner to result in the same aggregate amount of expenditures after such adjustment as would otherwise have been made for such services for 2005 or 2006, respectively, as estimated by the Secretary, if this paragraph did not apply.

(F) Beginning with 2006, the Secretary shall annually increase the basic case-mix adjusted payment amounts established under this paragraph, by an amount determined by—

(i) applying the estimated growth in expenditures for drugs and biologicals (including erythropoietin) that are separately billable to the component of the basic case-mix adjusted system described in subparagraph (B)(ii); and

(ii) converting the amount determined in clause (i) to an increase applicable to the basic case-mix adjusted payment amounts established under subparagraph (B).

Except as provided in subparagraph (G), nothing in this paragraph or paragraph (14) shall be construed as providing for an update to the composite rate component of the basic case-mix adjusted system under subparagraph (B) or under the system under paragraph (14).

(G) The Secretary shall increase the amount of the composite case-mix rate component of the basic case-mix adjusted system under subparagraph (B) for dialysis services—

(i) furnished on or after January 1, 2006, and before April 1, 2007, by 1.6 percent above the amount of such composite case-mix rate component for such services furnished on December 31, 2005;

(ii) furnished on or after April 1, 2007, and before January 1, 2009, by 1.6 percent above the amount of such composite rate component for such services furnished on March 31, 2007;

(iii) furnished on or after January 1, 2009, and before January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2008; and

(iv) furnished on or after January 1, 2010, by 1.0 percent above the amount of such composite rate component for such services furnished on December 31, 2009.

(H) There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of the case-mix system, relative weights, payment
amounts, the geographic adjustment factor, or the update for the system established under this paragraph, or the determination of the difference between medicare payment amounts and acquisition costs for separately billed drugs and biologicals (including erythropoietin) under this paragraph and paragraph (13).

(13)(A) Subject to paragraph (14), the payment amounts under this subchapter for separately billed drugs and biologicals furnished in a year, beginning with 2004, are as follows: 
(i) For such drugs and biologicals (other than erythropoietin) furnished in 2004, the amount determined under section 1395ww(o)(1)(A)(v) of this title for the drug or biological.

(ii) For such drugs and biologicals (including erythropoietin) furnished in 2005, the acquisition cost of the drug or biological, as determined by the Inspector General reports to the Secretary as required by section 623(c) of the Medicare Prescription Drug Improvement, and Modernization Act of 2003. Insofar as the Inspector General has not determined the acquisition cost with respect to a drug or biological, the Secretary shall determine the payment amount for such drug or biological.

(iii) For such drugs and biologicals (including erythropoietin) furnished in 2006 and subsequent years, such acquisition cost or the amount determined under section 1395w-3a of this title for the drug or biological, as the Secretary may specify.

(B) Drugs and biologicals (including erythropoietin) which were separately billed under this subsection on the day before December 8, 2003, shall continue to be separately billed on and after such date, subject to paragraph (14).

(14)(A)(i) Subject to subparagraph (E), for services furnished on or after January 1, 2011, the Secretary shall implement a payment system under which a single payment is made under this subchapter to a provider of services or a renal dialysis facility for renal dialysis services furnished on or after January 1, 2011, in a form and manner specified by the Secretary.

(ii) In implementing the system under this paragraph, the Secretary shall ensure that the estimated total amount of payments under this subchapter for 2011 for renal dialysis services shall equal 98 percent of the estimated total amount of payments for renal dialysis services, including payments under paragraph (12)(B)(ii), that would have been made under this subchapter with respect to services furnished in 2011 if such system had not been implemented. In making the estimation under subclause (i), the Secretary shall use per patient utilization data from 2007, 2008, or 2009, whichever has the lowest per patient utilization.

(B) For purposes of this paragraph, the term "renal dialysis services" includes—

(i) items and services included in the composite rate for renal dialysis services as of December 31, 2010; 

(ii) erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of end stage renal disease; 

(iii) other drugs and biologicals that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this subchapter, and any oral equivalent form of such drug or biological; and 

(iv) diagnostic laboratory tests and other items and services not described in clause (i) that are furnished to individuals for the treatment of end stage renal disease.

Such term does not include vaccines.

(C) The system under this paragraph may provide for payment on the basis of services furnished during a week or month or such other appropriate unit of payment as the Secretary specifies.

(D) Such system—

(i) shall include a payment adjustment based on case mix that may take into account patient weight, body mass index, comorbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors; 

(ii) shall include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variations in the amount of erythropoiesis stimulating agents necessary for anemia management; 

(iii) shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent; and 

(iv) may include such other payment adjustments as the Secretary determines appropriate, such as a payment adjustment—

(I) for pediatric providers of services and renal dialysis facilities; 

(II) by a geographic index, such as the index referred to in paragraph (12)(D), or the Secretary determines to be appropriate; and 

(III) for providers of services or renal dialysis facilities located in rural areas.

The Secretary shall take into consideration the unique treatment needs of children and young adults in establishing such system.

(E)(i) The Secretary shall provide for a four-year phase-in (in equal increments) of the payment amount under the payment system established under this paragraph, with such payment amount being fully implemented for renal dialysis services furnished on or after January 1, 2014.

(ii) A provider of services or renal dialysis facility may make a one-time election to be excluded from the phase-in under clause (i) and be paid entirely based on the payment amount under the payment system under this paragraph. Such an election shall be made prior to January 1, 2011, in a form and manner specified by the Secretary, and is final and may not be rescinded.

(iii) The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is ap-
applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such adjustment; (F)(i)(I) Subject to subclause (II) and clause (ii), beginning in 2012, the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

(II) For 2012 and each subsequent year, after determining the increase factor described in subclause (I), the Secretary shall reduce such increase factor by the productivity adjustment described in section 1395ww(b)(3)(B)(xii) of this title. The application of the preceding sentence may result in such increase factor being less than 0.0 for a year, and may result in payment rates under the payment system under this paragraph for a year being less than such payment rates for the preceding year.

(ii) For years during which a phase-in of the payment system pursuant to subparagraph (E) is applicable, the following rules shall apply to the portion of the payment under the system that is based on the payment of the composite rate that would otherwise apply if the system under this paragraph had not been enacted:

(I) The update under clause (i) shall not apply.

(II) Subject to clause (i)(II), the Secretary shall annually increase such composite rate by the ESRD market basket percentage increase factor described in clause (i)(I).

(G) There shall be no administrative or judicial review under section 1395ff of this title, section 1395ff of this title, or otherwise of the determination of payment amounts under subparagraph (A), the establishment of an appropriate unit of payment under subparagraph (C), the identification of renal dialysis services included in the bundled payments under subparagraph (D), the application of the phase-in under subparagraph (E), and the establishment of the market basket percentage increase factors under subparagraph (F).

(H) Erythropoiesis stimulating agents and other drugs and biologicals shall be treated as prescribed and dispensed or administered and available only under part B if they are—

(i) furnished to an individual for the treatment of end stage renal disease; and

(ii) included in subparagraph (B) for purposes of payment under this paragraph.

(c) Renal disease network areas; coordinating councils, executive committees, and medical review boards; national end stage renal disease medical information system; functions of network organizations

(1)(A)(i) For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall, in accordance with such criteria as he finds necessary to assure the performance of the responsibilities and functions specified in paragraph (2)—

(I) establish at least 17 end stage renal disease network areas, and

(II) for each such area, designate a network administrative organization which, in accordance with regulations of the Secretary, shall establish (aa) a network council of renal dialysis and transplant facilities located in the area and (bb) a medical review board, which has a membership including at least one patient representative and physicians, nurses, and social workers engaged in treatment relating to end stage renal disease.

The Secretary shall publish in the Federal Register a description of the geographic area that he determines, after consultation with appropriate professional and patient organizations, constitutes each network area and the criteria on the basis of which such determination is made.

(ii)(I) In order to determine whether the Secretary should enter into, continue, or terminate an agreement with a network administrative organization designated for an area established under clause (i), the Secretary shall develop and publish in the Federal Register standards, criteria, and procedures to evaluate an applicant organization’s capabilities to perform (and, in the case of an organization with which such an agreement is in effect, actual performance of) the responsibilities described in paragraph (2).

(C) The Secretary shall evaluate each applicant based on quality and scope of services and may not accord more than 20 percent of the weight of the evaluation to the element of price.

(II) An agreement with a network administrative organization may be terminated by the Secretary only if he finds, after applying such standards and criteria, that the organization has failed to perform its prescribed responsibilities effectively and efficiently. If such an agreement is to be terminated, the Secretary shall select a successor to the agreement on the basis of competitive bidding and in a manner that provides an orderly transition.

(B) At least one patient representative shall serve as a member of each network council and each medical review board.

(2) The network organizations of each network shall be responsible, in addition to such other duties and functions as may be prescribed by the Secretary, for—
(A) encouraging, consistent with sound medical practice, the use of those treatment settings most compatible with the successful rehabilitation of the patient and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs;

(B) developing criteria and standards relating to the quality and appropriateness of patient care and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs; and network goals with respect to the placement of patients in self-care settings and undergoing or preparing for transplantation;

(C) evaluating the procedure by which facilities and providers in the network assess the appropriateness of patients for proposed treatment modalities;

(D) implementing a procedure for evaluating and resolving patient grievances;

(E) conducting on-site reviews of facilities and providers as necessary (as determined by a medical review board or the Secretary), utilizing standards of care established by the network organization to assure proper medical care;

(F) collecting, validating, and analyzing such data as are necessary to prepare the reports required by subparagraph (H) and to assure the maintenance of the registry established under paragraph (7);

(G) identifying facilities and providers that are not cooperating toward meeting network goals and assisting such facilities and providers in developing appropriate plans for correction and reporting to the Secretary on facilities and providers that are not providing appropriate medical care; and

(H) submitting an annual report to the Secretary on July 1 of each year which shall include a full statement of the network's goals, data on the network's performance in meeting its goals (including data on the comparative performance of facilities and providers with respect to the identification and placement of suitable candidates in self-care settings and transplantation and encouraging participation in vocational rehabilitation programs), identification of those facilities that have consistently failed to cooperate with network goals, and recommendations with respect to the need for additional or alternative services or facilities in the network in order to meet the network goals, including self-dialysis training, transplantation, and organ procurement facilities.

(3) Where the Secretary determines, on the basis of the data contained in the network's annual report and such other relevant data as may be available to him, that a facility or provider has consistently failed to cooperate with network plans and goals or to follow the recommendations of the medical review board, he may terminate or withhold certification of such facility or provider (for purposes of payment for services furnished to individuals with end stage renal disease) until he determines that such provider or facility is making reasonable and appropriate efforts to cooperate with the network's plans and goals. If the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

(4) The Secretary shall, in determining whether to certify additional facilities or expansion of existing facilities within a network, take into account the network's goals and performance as reflected in the network's annual report.

(5) The Secretary, after consultation with appropriate professional and planning organizations, shall provide such guidelines with respect to the planning and delivery of renal disease services as are necessary to assure network organizations in their development of their respective networks' goals to promote the optimum use of self-dialysis and transplantation by suitable candidates for such modalities.

(6) It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment. The Secretary shall consult with appropriate professional and network organizations and consider available evidence relating to developments in research, treatment methods, and technology for home dialysis and transplantation.

(7) The Secretary shall establish a national end stage renal disease registry the purpose of which shall be to assemble and analyze the data reported by network organizations, transplant centers, and other sources on all end stage renal disease patients in a manner that will permit—

(A) the preparation of the annual report to the Congress required under subsection (g) of this section;

(B) an identification of the economic impact, cost-effectiveness, and medical efficacy of alternative modalities of treatment;

(C) an evaluation with respect to the most appropriate allocation of resources for the treatment and research into the cause of end stage renal disease;

(D) the determination of patient mortality and morbidity rates, and trends in such rates, and other indices of quality of care; and

(E) such other analyses relating to the treatment and management of end stage renal disease as will assist the Congress in evaluating the end stage renal disease program under this section.

The Secretary shall provide for such coordination of data collection activities, and such consolidation of existing end stage renal disease data systems, as is necessary to achieve the purpose of such registry, shall determine the appropriate location of the registry, and shall provide
for the appointment of a professional advisory group to assist the Secretary in the formulation of policies and procedures relevant to the management of such registry.

The provisions of sections 1320c-6 and 1320c-9 of this title shall apply with respect to network administrative organizations (including such organizations as medical review boards) with which the Secretary has entered into agreements under this subsection.

(d) Donors of kidney for transplant surgery

Notwithstanding any provision to the contrary in section 426 of this title any individual who donates a kidney for transplant surgery shall be entitled to benefits under parts A and B of this subchapter with respect to such donation. Reimbursement for the reasonable expenses incurred by such an individual with respect to a kidney donation shall be made (without regard to the deductible, premium, and coinsurance provisions of this subchapter), in such manner as may be prescribed by the Secretary in regulations, for all reasonable preparatory, operation, and postoperation recovery expenses associated with such donation, including but not limited to the expense for which payment could be made if he were an eligible individual for purposes of parts A and B of this subchapter without regard to this subsection. Payments for postoperation recovery expenses shall be limited to the actual period of recovery.

(e) Reimbursement of providers, facilities, and nonprofit entities for costs of artificial kidney and automated dialysis peritoneal machines for home dialysis

(1) Notwithstanding any other provision of this subchapter, the Secretary may, pursuant to agreements with approved providers of services, renal dialysis facilities, and nonprofit entities which the Secretary finds can furnish equipment economically and efficiently, reimburse such providers, facilities, and nonprofit entities (without regard to the deductible and coinsurance provisions of this subchapter) for the reasonable cost of the purchase, installation, maintenance and reconditioning for subsequent use of artificial kidney and automated dialysis peritoneal machines (including supportive equipment) which are to be used exclusively by entitled individuals dialyzing at home.

(2) An agreement under this subsection shall require that the provider, facility, or other entity will—

(A) make the equipment available for use only by entitled individuals dialyzing at home;

(B) recondition the equipment, as needed, for reuse by such individuals throughout the useful life of the equipment, including modification of the equipment consistent with advances in research and technology;

(C) provide for full access for the Secretary to all records and information relating to the purchase, maintenance, and use of the equipment; and

(D) submit such reports, data, and information as the Secretary may require with respect to the cost, management, and use of the equipment.

(3) For purposes of this section, the term “supportive equipment” includes blood pumps, heparin pumps, bubble detectors, other alarm systems, and such other items as the Secretary may determine are medically necessary.

(f) Experiments, studies, and pilot projects

(1) The Secretary shall initiate and carry out, at selected locations in the United States, pilot projects under which financial assistance in the purchase of new or used durable medical equipment for renal dialysis is provided to individuals suffering from end stage renal disease at the time home dialysis is begun, with provision for a trial period to assure successful adaptation to home dialysis before the actual purchase of such equipment.

(2) The Secretary shall conduct experiments to evaluate methods for reducing the costs of the end stage renal disease program. Such experiments shall include (without being limited to) reimbursement for nurses and dialysis technicians to assist with home dialysis, and reimbursement to family members assisting with home dialysis.

(3) The Secretary shall conduct experiments to evaluate methods of dietary control for reducing the costs of the end stage renal disease program, including (without being limited to) the use of protein-controlled products to delay the necessity for, or reduce the frequency of, dialysis in the treatment of end stage renal disease.

(4) The Secretary shall conduct a comprehensive study of methods for increasing public participation in kidney donation and other organ donation programs.

(5) The Secretary shall conduct a full and complete study of the reimbursement of physicians for services furnished to patients with end stage renal disease under this subchapter, giving particular attention to the range of payments to physicians for such services, the average amounts of such payments, and the number of hours devoted to furnishing such services to patients at home, in renal disease facilities, in hospitals, and elsewhere.

(6) The Secretary shall conduct a study of the number of patients with end stage renal disease who are not eligible for benefits with respect to such disease under this subchapter (by reason of this section or otherwise), and of the economic impact of such noneligibility of such individuals. Such study shall include consideration of mechanisms whereby governmental and other health plans might be instituted or modified to permit the purchase of actuarially sound coverage for the costs of end stage renal disease.

(7) (A) The Secretary shall establish protocols on standards and conditions for the reuse of dialyzer filters for those facilities and providers which voluntarily elect to reuse such filters.

(B) With respect to dialysis services furnished on or after January 1, 1988 (or July 1, 1988, with respect to protocols that relate to the reuse of bloodlines), no dialysis facility may reuse dialysis supplies (other than dialyzers filters) unless the Secretary has established a protocol with respect to the reuse of such supplies and the facility follows the protocol so established.

(C) The Secretary shall incorporate protocols established under this paragraph, and the requirement of subparagraph (B), into the requirements for facilities prescribed under subsection...
(b)(1)(A) of this section and failure to follow such a protocol or requirement subjects such a facility to denial of participation in the program established under this section and to denial of payment for dialysis treatment not furnished in compliance with such a protocol or in violation of such requirement.

(8) The Secretary shall submit to the Congress no later than October 1, 1979, a full report on the experiments conducted under paragraphs (1), (2), (3), and (7), and the studies under paragraphs (4), (5), (6), and (7). Such report shall include any recommendations for legislative changes which the Secretary finds necessary or desirable as a result of such experiments and studies.

(g) Conditional approval of dialysis facilities; restriction-of-payments notice to public and facility; notice and hearing; judicial review

(1) In any case where the Secretary—
(A) finds that a renal dialysis facility is not in substantial compliance with requirements for such facilities prescribed under subsection (b)(1)(A) of this section,
(B) finds that the facility’s deficiencies do not immediately jeopardize the health and safety of patients, and
(C) has given the facility a reasonable opportunity to correct its deficiencies,
the Secretary may, in lieu of terminating approval of the facility, determine that payment under this subchapter shall be made to the facility only for services furnished to individuals who were patients of the facility before the effective date of the notice.

(2) The Secretary’s decision to restrict payments under this subsection shall be made effective only after such notice to the public and to the facility as may be prescribed in regulations, and shall remain in effect until (A) the Secretary finds that the facility is in substantial compliance with the requirements under subsection (b)(1)(A) of this section, or (B) the Secretary terminates the agreement under this subchapter with the facility.

(3) A facility dissatisfied with a determination by the Secretary under paragraph (1) shall be entitled to a hearing thereon by the Secretary (after reasonable notice) to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary’s final decision after such hearing as is provided in section 405(g) of this title, except that, in so applying such sections and in applying section 405(i) of this title thereto, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(h) Quality incentives in the end-stage renal disease program

(1) Quality incentives
(A) In general

With respect to renal dialysis services (as defined in subsection (b)(14)(B)) furnished on or after January 1, 2012, in the case of a provider of services or a renal dialysis facility that does not meet the requirement described in subparagraph (B) with respect to the year, payments otherwise made to such provider or facility under the system under subsection (b)(14) for such services shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary.

(B) Requirement

The requirement described in this subparagraph is that the provider or facility meets (or exceeds) the total performance score under paragraph (3) with respect to performance standards established by the Secretary with respect to measures specified in paragraph (2).

(C) No effect in subsequent years

The reduction under subparagraph (A) shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the single payment amount under the system under paragraph (14) in a subsequent year.

(2) Measures

(A) In general

The measures specified under this paragraph with respect to the year involved shall include—
(i) measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management and measures on dialysis adequacy;
(ii) to the extent feasible, such measure (or measures) of patient satisfaction as the Secretary shall specify; and
(iii) such other measures as the Secretary specifies, including, to the extent feasible, measures on—
(I) iron management;
(II) bone mineral metabolism; and
(III) vascular access, including for maximizing the placement of arterial venous fistula.

(B) Use of endorsed measures

(i) In general

Subject to clause (ii), any measure specified by the Secretary under subparagraph (A)(iii) 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.

(C) Updating measures

The Secretary shall establish a process for updating the measures specified under subparagraph (A) in consultation with interested parties.

(D) Consideration

In specifying measures under subparagraph (A), the Secretary shall consider the
availability of measures that address the unique treatment needs of children and young adults with kidney failure.

(3) Performance scores

(A) Total performance score

(i) In general

Subject to clause (ii), the Secretary shall develop a methodology for assessing the total performance of each provider of services and renal dialysis facility based on performance standards with respect to the measures selected under paragraph (2) for a performance period established under paragraph (4)(D) (in this subsection referred to as the “total performance score”).

(ii) Application

For providers of services and renal dialysis facilities that do not meet (or exceed) the total performance score established by the Secretary, the Secretary shall ensure that the application of the methodology developed under clause (i) results in an appropriate distribution of reductions in payment under paragraph (1) among providers and facilities achieving different levels of total performance scores, with providers and facilities achieving the lowest total performance scores receiving the largest reduction in payment under paragraph (1)(A).

(iii) Weighting of measures

In calculating the total performance score, the Secretary shall weight the scores with respect to individual measures calculated under subparagraph (B) to reflect priorities for quality improvement, such as weighting scores to ensure that providers of services and renal dialysis facilities have strong incentives to meet or exceed anemia management and dialysis adequacy performance standards, as determined appropriate by the Secretary.

(B) Performance score with respect to individual measures

The Secretary shall also calculate separate performance scores for each measure, including for dialysis adequacy and anemia management.

(4) Performance standards

(A) Establishment

Subject to subparagraph (E), the Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period with respect to a year (as established under subparagraph (D)).

(B) Achievement and improvement

The performance standards established under subparagraph (A) shall include levels of achievement and improvement, as determined appropriate by the Secretary.

(C) Timing

The Secretary shall establish the performance standards under subparagraph (A) prior to the beginning of the performance period for the year involved.

(D) Performance period

The Secretary shall establish the performance period with respect to a year. Such performance period shall occur prior to the beginning of such year.

(E) Special rule

The Secretary shall initially use as the performance standard for the measures specified under paragraph (2)(A)(i) for a provider of services or a renal dialysis facility the lesser of—

(i) the performance of such provider or facility for such measures in the year selected by the Secretary under the second sentence of subsection (b)(14)(A)(ii); or

(ii) a performance standard based on the national performance rates for such measures in a period determined by the Secretary.

(5) Limitation on review

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

(A) The determination of the amount of the payment reduction under paragraph (1).

(B) The establishment of the performance standards and the performance period under paragraph (4).

(C) The specification of measures under paragraph (2).

(D) The methodology developed under paragraph (3) that is used to calculate total performance scores and performance scores for individual measures.

(6) Public reporting

(A) In general

The Secretary shall establish procedures for making information regarding performance under this subsection available to the public, including—

(i) the total performance score achieved by the provider of services or renal dialysis facility under paragraph (3) and appropriate comparisons of providers of services and renal dialysis facilities to the national average with respect to such scores; and

(ii) the performance score achieved by the provider or facility with respect to individual measures.

(B) Opportunity to review

The procedures established under subparagraph (A) shall ensure that a provider of services and a renal dialysis facility has the opportunity to review the information that is to be made public with respect to the provider or facility prior to such data being made public.

(C) Certificates

(i) In general

The Secretary shall provide certificates to providers of services and renal dialysis facilities who furnish renal dialysis services under this section to display in pa-
tient areas. The certificate shall indicate the total performance score achieved by the provider or facility under paragraph (3).

(ii) Display
Each facility or provider receiving a certificate under clause (i) shall prominently display the certificate at the provider or facility.

(D) Web-based list
The Secretary shall establish a list of providers of services and renal dialysis facilities who furnish renal dialysis services under this section that indicates the total performance score and the performance score for individual measures achieved by the provider and facility under paragraph (3). Such information shall be posted on the Internet website of the Centers for Medicare & Medicaid Services in an easily understandable format.


REFERENCES IN TEXT
Parts A and B, referred to in text, are classified to sections 1395g et seq. and 1395i et seq., respectively, of this title.


Subsection (b)(14) of this section, referred to in subsec. (c)(7)(A), was repealed, and subsec. (h) was redesignated (g), by Pub. L. 100–203, title IV, §§ 4036(d)(5)(C), (D), Dec. 22, 1987, 101 Stat. 1330–80.

AMENDMENTS
2010—Subsec. (b)(14)(F)(1). Pub. L. 111–148, § 3401(h)(1), designated existing provisions as subcl. (I), substituted “Subclause (II) and clause (ii)” for “clause (ii)” and struck out “minus 1.0 percentage point” before period at end, and added subcl. (II).

Subsec. (b)(14)(F)(2). Pub. L. 111–148, § 3401(h)(2), substituted “Subject to clause (ii)(I)” for “The” and “and clause (i)(I)” for “clause (i) minus 1.0 percentage point”.

2008—Subsec. (b)(12)(F). Pub. L. 110–275, § 153(a)(2), (b)(3)(A)(ii), substituted “Subject to paragraph (14), in concluding provisions, inserted “or paragraph (14)” after “this paragraph” and “or under the system under paragraph (14)” after “paragraph (B)”, and added subpars. (C) and (D).


Subsec. (b)(13)(A). Pub. L. 110–275, § 153(b)(3)(A)(ii)(II), redesignated cl. (i) as subpar. (B), inserted “subject to paragraph (14)” before period at end, and struck out cl. (i) which read as follows: “Nothing in this paragraph, section 1396u(c) of this title, section 1396w–3a of this title, or section 1396w–3b of this title shall be construed as requiring or authorizing the bundling of payment for drugs and biologicals into the basic case-mix adjusted payment system under this paragraph.”


REFERENCES IN TEXT
Parts A and B, referred to in text, are classified to sections 1395c et seq. and 1395i et seq., respectively, of this title.


Section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (b)(12)(B)(ii), (13)(A)(ii)(I), is section 623(c) of Pub. L. 108–173, which is set out as a note under this section.

Subsection (g) of this section, referred to in subsec. (c)(7)(A), was repealed, and subsec. (h) was redesignated (g), by Pub. L. 100–203, title IV, §§ 4036(d)(5)(C), (D), Dec. 22, 1987, 101 Stat. 1330–80.
rate payment amounts for such services furnished on December 31, 2004” before period at end.


Subsec. (g). Pub. L. 100–203, § 4086(d)(5)(C), (D), redesignated subsec. (h) as (g) and redesignated former subsec. (h) as (g) which directed the Secretary to submit to Congress on July 1, 1979, and on July 1 of each year thereafter a report on end stage renal disease program.

Subsec. (h). Pub. L. 100–203, § 4086(d)(5)(D), redesignated subsec. (h) as (g).

Pub. L. 100–93 added subsec. (h).
Subsec. (c)(6). Pub. L. 99–509, §835(i)(b), inserted "and that the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment" at end of first sentence.

Subsec. (c)(7). Pub. L. 99–509, §835(k)(1), added par. (7). Pub. L. 99–509, §835(k)(5), amended par. (7) generally. Prior to amendment, par. (7) read as follows: "The Secretary shall conduct a study of the medical appropriateness and safety of cleaning and reusing dialysis filters by home dialysis patients. In such cases in which the Secretary determines that such home cleaning and reuse of filters is a medically sound procedure, the Secretary shall conduct experiments to evaluate such home cleaning and reuse as a method of reducing the costs of the end stage renal disease program."

1984—Subsecs. (a), (b)(1), (2)(A), (3), (8). Pub. L. 98–369, §2354(b)(41), substituted "end stage" for "end-stage" wherever appearing.


Pub. L. 98–369, §2323(c), added par. (11).

Subsec. (c)(3). Pub. L. 98–369, §2323(a), inserted proviso that if the Secretary determines that the facility's or provider's failure to cooperate with network plans and goals does not jeopardize patient health or safety or justify termination of certification, he may instead, after reasonable notice to the provider or facility and to the public, impose such other sanctions as he determines to be appropriate, which sanctions may include denial of reimbursement with respect to some or all patients admitted to the facility after the date of notice to the facility or provider, and graduated reduction in reimbursement for all patients.

1983—Subsec. (b)(2). Pub. L. 98–21 inserted "or section 1395wv of this title (if applicable)" after "section 1395v(c) of this title".

1961—Subsec. (b)(2)(B). Pub. L. 97–35, §2145(a)(1), (2), substituted "section 1395rvw of this title" for "section 1395v(c) of this title" and struck out provisions that such regulations provide for the implementation of appropriate incentives for encouraging more efficient and effective delivery of services, and include a system for classifying comparable providers and facilities, and prospectively set rates or target rates with arrangements for sharing such reductions in costs as may be attributable to more efficient and effective delivery of services.

Subsec. (b)(3)(B). Pub. L. 97–35, §2145(a)(3), substituted "section 1395rv of this title" for "section 1395rv(c) of this title", and provided that: "The amendments made by subsection (a)(1) of this section shall apply to applications filed on or after January 1, 1961.".

Pub. L. 98–369, §2323(d), added par. (11).

Amendment by Pub. L. 97–35, §2145(a)(2), substituted "or network areas established under the amendment made by subsection (d)(1) of this section" for "or facility".

Effective Date of 1994 Amendment

Effective Date of 1993 Amendment
Amendment by Pub. L. 103–66 applicable to erythropoietin furnished on or after Jan. 1, 1994, see section 1395f(c) of Pub. L. 103–66, set out as a note under section 1395f of this title.

Effective Date of 1990 Amendment
Section 4201(c)(2) of Pub. L. 101–508 provided that: "The amendments made by this section shall apply to erythropoietin furnished on or after January 1, 1991."

Amendment by section 4201(d)(2) of Pub. L. 101–508 applicable to items and services furnished on or after July 1, 1991, see section 4201(d)(3)(4) of Pub. L. 101–508, set out as a note under section 1395x of this title.

Effective Date of 1989 Amendment
Section 6203(b)(3) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section] shall apply with respect to services furnished on or after February 1, 1990."

Effective Date of 1987 Amendments
Amendment by section 4065(b) of Pub. L. 100–233 effective Jan. 1, 1988, see section 4065(c) of Pub. L. 100–233, set out as a note under section 1395x of this title.

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 5(a) of Pub. L. 100–93, set out as a note under section 1395a–7 of this title.

Effective Date of 1986 Amendments
Section 9335(a)(3) of Pub. L. 99–509 provided that: "The amendments made by paragraph (2) [amending this section] shall apply to applications filed on or after the date of the enactment of this Act [Oct. 21, 1986]."

Section 9335(j)(2) of Pub. L. 99–509, as amended by Pub. L. 100–203, title IV, §405(i)(21)(C), Dec. 22, 1987, 101 Stat. 1320–131, provided that: "The amendments made by subsections (e), (f), and (g) of this section and amendments made by subsections (a) and (b) of this section (which effectively encourages the efficient delivery of dialysis services and provides incentives for the increased use of home dialysis)" for "or other basis".


Subsec. (b)(6). Pub. L. 97–35, §2145(a)(5), (6), substituted "except as may be provided in regulations under paragraph (7)" for "section 1395v(c) of this title" and struck out provisions that such regulations provide for the implementation of appropriate incentives for encouraging more efficient and effective delivery of services, and include a system for classifying comparable providers and facilities, and prospectively set rates or target rates with arrangements for sharing such reductions in costs as may be attributable to more efficient and effective delivery of services.

Pub. L. 98–617 realigned margin of par. (6).

Pub. L. 98–369, §2323(c), added par. (6).

Amendment by Pub. L. 97–35, §2145(a)(1), (2), substituted "section 1395rv of this title" for "section 1395rv(c) of this title", and provided that: "The amendments made by paragraph (1) [amending this section] shall apply to treatment furnished on or after January 1, 1987[.]" except that, until network administrative organizations are established under section 1881(c)(1)(A) of the Social Security Act [subsec. (c)(1)(A) of this section] (as amended by subsection (d)(1) of this section), the distribution of payments described in the last sentence of section 1881(b)(7) of such Act shall be made based on the distribution of payments under section 1881 of such Act to network administrative organizations for fiscal year 1986." [Section 4085(i)(21) of Pub. L. 100–203 provided that the amendment of section 9335(j)(2) of Pub. L. 99–509, set out above, by section 4985(i)(21)(C) of Pub. L. 100–203 is effective as if included in the enactment of Pub. L. 99–509.]

Section 9335(j) of Pub. L. 99–509 provided that: "The amendments made by subsections (e), (f), and (g) [amending this section] shall apply to network administrative organizations designated for network areas established under the amendment made by subsection (d)(1) [amending this section]."

Effective Date of 1984 Amendments
Amendment by Pub. L. 98–617 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L. 98–369, see section 3(c) of Pub. L. 98–617, set out as a note under section 1395f of this title.

Amendment by section 2323(c) of Pub. L. 98–369 applicable to services furnished on or after Sept. 1, 1984, see section 2323(d) of Pub. L. 98–369, set out as a note under section 1395f of this title.
Section 235(b) of Pub. L. 98–369 provided that: "The amendment made by this section [amending this section] shall apply to determinations made by the Secretary on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 235(b)(4) 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 604(a)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1983 Amendment**

Amendment by 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 1320a–1 of this title.

**Effective Date of 1981 Amendment**

Section 2145(b) of Pub. L. 97–33 provided that: "The amendments made by subsection (a) [amending this section] apply to services furnished on or after October 1, 1981, and the Secretary of Health and Human Services shall conduct two studies with respect to drugs and biologicals for which a billing code exists (under the provisions of law in effect on Apr. 1, 1981, but not to be construed as changing the month of June 1978, and except that provisions of this section] not later than October 1, 1981."

**Effective Date**

Section effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility’s or provider’s first accounting period beginning after the last day of the twelfth month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as an Effective Date of 1978 Amendment note under section 1395ww of this title.

**Construction of 2008 Amendment**

Pub. L. 110–275, title I, §115(b)(4), July 15, 2008, 122 Stat. 2556, provided that: "Nothing in this subsection [amending this section and sections 1395x and 1395y of this title and repealing provisions set out as a note under this section] or the amendments made by this subsection shall be construed as authorizing or requiring the Secretary of Health and Human Services to make payments under the payment system implemented under paragraph (14)(A)(i) of section 1861(b) of the Social Security Act [42 U.S.C. 1395rr(b)], as added by paragraph (1), for any unrecovered amount for any bad debt attributable to deductible and coinsurance on items and services not included in the basic case-mix adjusted composite rate under paragraph (12) of such section as in effect before the date of the enactment of this Act [July 15, 2008]."

**Inspector General Studies on ESRD Drugs**

Pub. L. 108–173, title VI, §623(c), Dec. 8, 2003, 117 Stat. 2515, which provided for establishment of a demonstration project, to be conducted for the 3-year period beginning on Jan. 1, 2006, of the use of a fully case-mix adjusted payment system for end stage renal disease services that bundled into payment rates amounts for drugs and biologicals (including erythropoietin) furnished to end stage renal disease patients under the Medicare program which were separately billed by end stage renal disease facilities as of Dec. 8, 2003, and clinical laboratory tests related to such drugs and biologicals, and which authorized appropriations for the demonstration project, was repealed by Pub. L. 110–275, title I, §153(b)(3)(C), July 15, 2008, 122 Stat. 2556.

**Report on a Bundled Prospective Payment System for End Stage Renal Disease Services**


- "(1) REPORT.—
  "(A) IN GENERAL.—Not later than October 1, 2005, the Secretary of Health and Human Services shall submit to Congress a report detailing the elements and features for the demonstration of a bundled prospective payment system for services furnished by end stage renal disease facilities including, to the maximum extent feasible, bundles of drugs, clinical laboratory tests, and other items that are separately billed by such facilities. The report shall include a description of the methodology to be used for the establishment of payment rates, including components of the new system described in paragraph (2).
  "(B) RECOMMENDATIONS.—The Secretary shall include in such report recommendations on elements, features, and methodology for a bundled prospective payment system or other issues related to such system as the Secretary determines to be appropriate.
  "(2) ELEMENTS AND FEATURES OF A BUNDLED PROSPECTIVE PAYMENT SYSTEM.—The report required under paragraph (1) shall include the following elements and features of a bundled prospective payment system:
    "(A) BUNDLE OF ITEMS AND SERVICES.—A description of the bundle of items and services to be included under the prospective payment system.
    "(B) CASE MIX.—A description of the case-mix adjustment to account for the relative resource use of different types of patients.
    "(C) WAGE INDEX.—A description of an adjustment to account for geographic differences in wages.
    "(D) RURAL AREAS.—The appropriateness of establishing a specific payment adjustment to account for additional costs incurred by rural facilities.

- "(B) NEW DRUGS.—The second study under paragraph (1) shall be conducted with respect to such drugs and biologicals for which a billing code does not exist prior to January 1, 2004.
  "(C) MATTERS STUDIED.—Under each study conducted under paragraph (1), the Inspector General shall—
    "(A) determine the difference between the amount of payment made to end stage renal disease facilities under title XVIII of the Social Security Act (this subchapter) for such drugs and biologicals and the acquisition cost of such facilities for such drugs and biologicals and which are separately billed by end stage renal disease facilities, and
    "(B) estimate the rates of growth of expenditures for such drugs and biologicals billed by such facilities.
  "(4) REPORTS.—
    "(A) EXISTING ESRD DRUGS.—Not later than April 1, 2004, the Inspector General shall report to the Secretary [of Health and Human Services] on the study described in paragraph (2)(A).
    "(B) NEW ESRD DRUGS.—Not later than April 1, 2006, the Inspector General shall report to the Secretary on the study described in paragraph (2)(B)."
"(E) OTHER ADJUSTMENTS.—Such other adjustments as may be necessary to reflect the variation in costs incurred by facilities in caring for patients with end stage renal disease.

"(F) UPDATE FRAMEWORK.—A methodology for appropriate updates under the prospective payment system.

"(G) ADDITIONAL RECOMMENDATIONS.—Such other matters as the Secretary determines to be appropriate."

PROHIBITION ON EXCEPTIONS


"(A) IN GENERAL.—Subject to subparagraphs (B), (C), and (D), the Secretary of Health and Human Services may not provide for an exception under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)) on or after December 31, 2000.

"(B) DEADLINE FOR NEW APPLICATIONS.—Subject to subparagraph (D), in the case of a facility that during 2000 did not file for an exception rate under such section, the facility may submit an application for an exception rate by not later than July 1, 2001."

"(C) PROTECTION OF APPROVED EXCEPTION RATES.—Any exception rate under such section in effect on December 31, 2000 (or, in the case of an application under subparagraph (B), as approved under such application) shall continue in effect so long as such rate is greater than the composite rate as updated by the amendment made by paragraph (1) [amending this section].

"(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2003, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term ‘pediatric facility’ means a renal facility at least 50 percent of whose patients are individuals under 18 years of age."

DEVELOPMENT OF ESRD MARKET BASKET

Pub. L. 106–554, §1(a)(6) [title IV, §422(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that:

"(1) DEVELOPMENT.—The Secretary of Health and Human Services shall collect data and develop an ESRD market basket whereby the Secretary can estimate, before the beginning of a year, the percentage by which the costs for the year of the mix of labor and nonlabor goods and services included in the ESRD composite index under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)) will exceed the costs of such mix of goods and services for the preceding year. In developing such index, the Secretary may take into account measures of changes in—

"(A) technology used in furnishing dialysis services;

"(B) the manner or method of furnishing dialysis services; and

"(C) the amounts by which the payments under such section for all services billed by a facility for a year exceed the aggregate allowable audited costs of such services for such facility for such year.

"(2) REPORT.—The Secretary of Health and Human Services shall submit to Congress a report on the index developed under paragraph (1) no later than July 1, 2002, and shall include in the report recommendations on the appropriateness of an annual or periodic update mechanism for renal dialysis services under the medicare program under title XVIII of the Social Security Act [this subchapter] based on such index."

INCLUSION OF ADDITIONAL SERVICES IN COMPOSITE RATE

Pub. L. 106–554, §1(a)(6) [title IV, §422(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–517, provided that:

"(1) DEVELOPMENT.—The Secretary of Health and Human Services shall develop a system which includes, to the maximum extent feasible, in the composite rate used for payment under section 1881(b)(7) of the Social Security Act (42 U.S.C. 1395rr(b)(7)), payment for clinical diagnostic laboratory tests and drugs (including drugs paid under section 1881(b)(11)(B) of such Act (42 U.S.C. 1395rr(b)(11)(B)) that are routinely used in furnishing dialysis services to medicare beneficiaries but which are currently separately billable by renal dialysis facilities.

"(2) REPORT.—The Secretary shall include, as part of the report submitted under subsection (b)(2) [set out above], a report on the system developed under paragraph (1) and recommendations on the appropriateness of incorporating the system into medicare payment for renal dialysis services."

GAO STUDY ON ACCESS TO SERVICES

Pub. L. 106–554, §1(a)(6) [title IV, §422(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–517, provided that:

"(1) STUDY.—The Comptroller General of the United States shall study access of medicare beneficiaries to renal dialysis services. Such study shall include whether there is a sufficient supply of facilities to furnish needed renal dialysis services, whether medicare payment levels are appropriate, taking into account audited costs of facilities for all services furnished, to ensure continued access to such services, and improvements in access (and quality of care) that may result in the increased use of long nightly and short daily hemodialysis modalities.

"(2) REPORT.—Not later than January 1, 2003, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1)."

SPECIAL RULE FOR PAYMENT FOR 2001

Pub. L. 106–554, §1(a)(6) [title IV, §422(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A–517, provided that: "Notwithstanding the amendment made by subsection (a)(1) [amending this section], for purposes of making payments under section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) for dialysis services furnished during 2001, the composite rate payment under paragraph (7) of such section—

"(1) for services furnished on or after January 1, 2001, and before April 1, 2001, shall be the composite rate payment determined under the provisions of law in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

"(2) for services furnished on or after April 1, 2001, and before January 1, 2002, shall be the composite rate payment (as determined taking into account the amendment made by subsection (a)(1)) increased by a transitional percentage allowance equal to 0.39 percent (to account for the timing of implementation of the CPI update)."

STUDY ON PAYMENT LEVEL FOR HOME HEMODIALYSIS

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §222(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–352, provided that: "The Medicare Payment Advisory Commission shall conduct a study on the appropriateness of the differential in payment under the medicare program for hemodialysis services furnished in a facility and such services furnished in a home. Not later than 18 months after the date of the enactment of this Act [Nov. 29, 1999], the Commission shall submit to Congress a report on such study and shall include recommendations regarding changes in medicare payment policy in response to the study."

RENAI DIALYSIS-RELATED SERVICES

Pub. L. 105–33, title IV, §4558, Aug. 5, 1997, 111 Stat. 463, provided that:

"(a) AUDITING OF COST REPORTS.—Beginning with cost reports for 1996, the Secretary shall audit cost reports of each renal dialysis provider at least once every 3 years.

"(b) IMPLEMENTATION OF QUALITY STANDARDS.—The Secretary of Health and Human Services shall develop,
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by not later than January 1, 1999, and implement, by not later than January 1, 2000, a method to measure and report quality of renal dialysis services provided under the medicare program under title XVIII of the Social Security Act [this subchapter]."

PROPAC STUDY ON ESRD COMPOSITE RATES

Section 4201(b) of Pub. L. 101–508 provided that:

"(1) IN GENERAL.—

"(A) STUDY.—The Prospective Payment Assessment Commission (in this subsection referred to as the ‘Commission’) shall conduct a study to determine the costs and services and profits associated with various modalities of dialysis treatments provided to end stage renal disease patients provided under title XVIII of the Social Security Act [this subchapter].

"(B) RECOMMENDATION.—Based on information collected for the study described in subparagraph (A), the Commission shall make recommendations to Congress regarding the method or methods and the levels at which the payments made for the facility component of dialysis services by providers of service and renal dialysis facilities under title XVIII of the Social Security Act should be established for dialysis services furnished during fiscal year 1995 and the methodology to be used to update such payments for subsequent fiscal years. In making recommendations concerning the appropriate methodology the Commission shall consider—

"(i) hemodialysis and other modalities of treatment,

"(ii) the appropriate services to be included in such payments,

"(iii) the adjustment factors to be incorporated including facility characteristics, such as hospital versus free-standing facilities, urban versus rural, size and mix of services,

"(iv) adjustments for labor and nonlabor costs,

"(v) comparative profit margins for all types of renal dialysis providers of service and renal dialysis facilities,

"(vi) adjustments for patient complexity, such as age, diagnosis, case mix, and pediatric services, and

"(vii) efficient costs related to high quality of care and positive outcomes for all treatment modalities.

"(2) REPORT.—Not later than June 1, 1992, the Commission shall submit a report to the Committee on Finance of the Senate, and the Committees on Ways and Means and Energy and Commerce of the House of Representatives on the study conducted under paragraph (1)(A) and shall include in the report the recommendations described in paragraph (1)(B), taking into account the factors described in paragraph (1)(B).

"(3) ANNUAL REPORT.—The Commission, not later than March 1 before the beginning of each fiscal year (beginning with fiscal year 1995) shall report its recommendations to the Committee on Finance of the Senate and the Committees on Ways and Means and Energy and Commerce of the House of Representatives on an appropriate change factor which should be used for updating payments for services rendered in that fiscal year. The Commission in making such report to Congress shall consider conclusions and recommendations available from the Institute of Medicine.’’ [Prospective Payment Assessment Commission (ProPAC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 4022(c)(2), (3) of Pub. L. 101–33, set out as a note under section 1395b–6 of this title. Section 4022(c)(2), (3) further provided that MedPAC was to be responsible for preparation and submission of reports required by law to be submitted by ProPAC, and that, for that purpose, any reference in law to ProPAC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.]

STAFF-ASSISTED HOME DIALYSIS DEMONSTRATION PROJECT


"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 9 months after the date of the enactment of this Act [Nov. 5, 1990], the Secretary of Health and Human Services shall establish and carry out a 3-year demonstration project to determine whether the services of a home dialysis staff assistant providing services to a patient during hemodialysis treatment at the patient’s home may be covered under the medicare program in a cost-effective manner that ensures patient safety.

"(2) NUMBER OF PARTICIPANTS.—The total number of eligible patients receiving services under the demonstration project established under paragraph (1) may not exceed 800.

"(b) PAYMENTS TO PARTICIPATING PROVIDERS AND FACILITIES.—

"(1) SERVICES FOR WHICH PAYMENT MAY BE MADE.—

"(A) IN GENERAL.—Under the demonstration project established under subsection (a), the Secretary shall make payments for 3 years under title XVIII of the Social Security Act [this subchapter] to providers of services (other than a skilled nursing facility) or renal dialysis facilities for services of a qualified home hemodialysis staff assistant (as described in subsection (d)) provided to an individual described in subsection (c) during hemodialysis treatment at the individual’s home in an amount determined under paragraph (2).

"(B) SERVICES DESCRIBED.—For purposes of subparagraph (A), the term ‘services of a home hemodialysis staff assistant’ means—

"(i) technical assistance with the operation of a hemodialysis machine in the patient’s home and with such patient’s care during in-home hemodialysis; and

"(ii) administration of medications within the patient’s home to maintain the patency of the extra corporeal circuit.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—Payment to a provider of services or renal dialysis facility participating in the demonstration project established under subsection (a) for the services described in subparagraph (A) shall be prospectively determined by the Secretary, made on a per treatment basis, and shall be in an amount determined under subparagraph (B).

"(B) DETERMINATION OF PAYMENT AMOUNT.—(i) The amount of payment made under subparagraph (A) shall be the product of—

"(I) the rate determined under clause (ii) with respect to a provider of services or a renal dialysis facility; and

"(II) the factor by which the labor portion of the composite rate determined under section 1881(b)(7) of the Social Security Act [subsec. (b)(7) of this section] is adjusted for differences in area wage levels.

"(ii) The rate determined under this clause, with respect to a provider of services or renal dialysis facility, shall be equal to the difference between—

"(I) two-thirds of the labor portion of the composite rate applicable under section 1881(b)(7) of such Act to the provider or facility, and

"(II) the product of the national median hourly wage for a home hemodialysis staff assistant and the national median average time expended in the provision of home hemodialysis staff assistant services (taking into account time expended in travel and predialysis patient care).

"(iii) For purposes of clause (ii)(II)—

"(I) the national median hourly wage for a home hemodialysis staff assistant and the national median average time expended for home hemodialysis staff assistant services shall be determined annually on the basis of the most recent data available, and

"(II) the national median hourly wage for a home hemodialysis staff assistant shall be the sum of 65 percent of the national median hourly wage for a licensed practical nurse and 35 percent
of the national median hourly wage for a registered nurse.

‘‘(C) Payment as Add-on to Composite Rate.—The amount of payment determined under this paragraph shall be in addition to the amount of payment otherwise made to the provider of services or renal dialysis facility under section 1881(b) of such Act.

‘‘(C) IndIVIDUALs Eligible to REceive Services Under Project.—

‘‘(1) In general.—An individual may receive services from a provider of services or renal dialysis facility participating in the demonstration project if—

‘‘(A) the individual is not a resident of a nursing facility;

‘‘(B) the individual is an end stage renal disease patient entitled to benefits under title XVIII of the Social Security Act [this subchapter];

‘‘(C) the individual’s physician certifies that the individual is confined to a bed or wheelchair and cannot transfer themselves [sic] from a bed to a chair;

‘‘(D) the individual has a serious medical condition (as specified by the Secretary) which would be exacerbated by travel to and from a dialysis facility;

‘‘(E) the individual is eligible for ambulance transportation to receive routine maintenance dialysis treatments, and, based on the individual’s medical condition, there is reasonable expectation that such transportation will be used by the individual for a period of at least 6 consecutive months, such that the cost of ambulance transportation can reasonably be expected to meet or exceed the cost of home hemodialysis staff assistance as provided under subsection (b)(2); and

‘‘(F) no family member or other individual is available to provide such assistance to the individual.

‘‘(2) Coverage of Individuals Currently Receiving Services.—Any individual who, on the date of the enactment of this Act [Nov. 5, 1990], is receiving staff assistance under the experimental authority provided under section 1881(f)(2) of the Social Security Act [subsec. (f)(2) of this section] shall be deemed to be an eligible individual for purposes of this subsection.

‘‘(3) Continuation of Coverage Upon Termination of Project.—Notwithstanding any provision of title XVIII of the Social Security Act, any individual receiving services under the demonstration project established under subsection (a) as of the date of the termination of the project shall continue to be eligible for home hemodialysis staff assistance after such date under such title on the same terms and conditions as applied under the demonstration project.

‘‘(d) Qualifications for Home Hemodialysis Staff Assistants.—For purposes of subsection (b), a home dialysis aide is qualified if the aide—

‘‘(1) meets minimum qualifications as specified by the Secretary; and

‘‘(2) meets any applicable qualifications as specified under the law of the State in which the home hemodialysis staff assistant is providing services.

‘‘(e) Reports.—

‘‘(1) Initial Status Report.—Not later than December 1, 1992, the Secretary shall submit to Congress a preliminary report on the status of the demonstration project established under subsection (a).

‘‘(2) Final Report.—Not later than December 31, 1992, the Secretary shall submit to Congress a final report evaluating the project, and shall include in such report recommendations regarding appropriate eligibility criteria and cost-control mechanisms for medicare coverage of the services of a home dialysis aide providing medical assistance to a patient during hemodialysis treatment at the patient’s home.

‘‘(f) Authorization of Appropriations.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841 of the Social Security Act [section 1395t of this title]) of not more than the following amounts to carry out the demonstration project established under subsection (a) (without regard to amounts appropriated in advance in appropriation Acts):

‘‘(1) For fiscal year 1991, $4,000,000.

‘‘(2) For fiscal year 1992, $4,000,000.

‘‘(3) For fiscal year 1993, $3,000,000.

‘‘(4) For fiscal year 1994, $2,000,000.

‘‘(5) For fiscal year 1995, $1,000,000.’’

Studies of End-Stage Renal Disease Program

Section 4038(d)(1)–(4) of Pub. L. 100–203 provided that:

‘‘(1) The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) shall arrange for a study of the end-stage renal disease program within the medicare program.

‘‘(2) Among other items, the study shall address—

‘‘(A) access to treatment by both individuals eligible for medicare benefits and those not eligible for such benefits;

‘‘(B) the quality of care provided to end-stage renal disease beneficiaries, as measured by clinical indicators, functional status of patients, and patient satisfaction;

‘‘(C) the effect of reimbursement on quality of treatment;

‘‘(D) major epidemiological and demographic changes in the end-stage renal disease population that may affect access to treatment, the quality of care, or the resource requirements of the program; and

‘‘(E) the adequacy of existing data systems to monitor these matters on a continuing basis.

‘‘(3) The Secretary shall submit to Congress, not later than 3 years after the date of the enactment of this Act [Dec. 22, 1987], a report on the study.

‘‘(4) The Secretary shall request the National Academy of Sciences, acting through the Institute of Medicine, to submit an application to conduct the study described in this section. If the Academy submits an acceptable application, the Secretary shall enter into an appropriate arrangement with the Academy for the conduct of the study. If the Academy does not submit an acceptable application to conduct the study, the Secretary may request one or more appropriate non-profit private entities to submit an application to conduct the study and may enter into an appropriate arrangement for the conduct of the study by the entity which submits the best acceptable application.’’

Rates for Dialysis Services


‘‘(A) the Department of Health and Human Services may, at any time, reduce the base rate for routine dialysis treatment in a free-standing facility and in a hospital-based facility under section 1881(b)(7) of the Social Security Act [subsec. (b)(7) of this section] at a level equal to the respective rate in effect as of May 15, 1986, reduced by $2.00. With respect to services furnished on or after January 1, 1991, and before January 1, 2000, such base rate shall be equal to the respective rate in effect as of September 30, 1990, unless the Secretary by $1.00. No change may be made in the base rate in effect as of September 30, 1990, unless the Secretary makes such change in accordance with notice and comment requirements set forth in section 1871(b)(1) of such Act [subsec. (b)(1) of this section].

‘‘(B) The amendment made by paragraph (1) (amending section 1881(c)(6) of such Act) shall apply to amounts transferred under section 1881(c)(6) of such Act for fiscal years 1994 and 1995.

Note—


(3) Effective date of coverage
An Individual\(^1\) who is deemed eligible for benefits under this subchapter under paragraph (1) or (2) shall be—

(A) entitled to benefits under the program under Part 1 as of the date of such deeming; and

(B) eligible to enroll in the program under Part 1B beginning with the month in which such deeming occurs.

(b) Pilot program for care of certain individuals residing in emergency declaration areas

(1) Program; purpose

(A) Primary pilot program

The Secretary shall establish a pilot program in accordance with this subsection to provide innovative approaches to furnishing comprehensive, coordinated, and cost-effective care under this subchapter to individuals described in paragraph (2)(A).

(B) Optional pilot programs

The Secretary may establish a separate pilot program, in accordance with this subsection, with respect to each geographic area subject to an emergency declaration (other than the declaration of June 17, 2009), in order to furnish such comprehensive, coordinated and cost-effective care to individuals described in subparagraph (2)(B) who reside in each such area.

(2) Individual described

For purposes of paragraph (1), an individual described in this paragraph is an individual who enrolls in part B, submits to the Secretary an application to participate in the applicable pilot program under this subsection, and—

(A) is an environmental exposure affected individual described in subsection (e)(2) who resides in or around the geographic area subject to an emergency declaration made as of June 17, 2009; or

\(^1\)So in original. Probably should not be capitalized.
(B) is an environmental exposure affected individual described in subsection (e)(3) who—

(i) is deemed under subsection (a)(2); and

(ii) meets such other criteria or conditions for participation in a pilot program under paragraph (1)(B) as the Secretary specifies.

(3) Flexible benefits and services

A pilot program under this subsection may provide for the furnishing of benefits, items, or services not otherwise covered or authorized under this subchapter, if the Secretary determines that furnishing such benefits, items, or services will further the purposes of such pilot program (as described in paragraph (1)).

(4) Innovative reimbursement methodologies

For purposes of the pilot program under this subsection, the Secretary—

(A) shall develop and implement appropriate methodologies to reimburse providers for furnishing benefits, items, or services for which payment is not otherwise covered or authorized under this subchapter, if such benefits, items, or services are furnished pursuant to paragraph (3); and

(B) may develop and implement innovative approaches to reimbursing providers for any benefits, items, or services furnished under this subsection.

(5) Limitation

Consistent with section 1395y(b) of this title, no payment shall be made under the pilot program under this subsection with respect to benefits, items, or services furnished to an environmental exposure affected individual (as defined in subsection (e)) to the extent that such individual is eligible to receive such benefits, items, or services through any other public or private benefits plan or legal agreement.

(6) Waiver authority

The Secretary may waive such provisions of this subchapter and subchapter XI as are necessary to carry out pilot programs under this subsection.

(7) Funding

For purposes of carrying out pilot programs under this subsection, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1395f of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, in such proportion as the Secretary determines necessary, to the Centers for Medicare & Medicaid Services Program Management Account.

(8) Waiver of budget neutrality

The Secretary shall not require that pilot programs under this subsection be budget neutral with respect to expenditures under this subchapter.

(c) Determinations

(1) By the Commissioner of Social Security

For purposes of this section, the Commissioner of Social Security, in consultation with the Secretary, and using the cost allocation method prescribed in section 401(g) of this title, shall determine whether individuals are environmental exposure affected individuals.

(2) By the Secretary

The Secretary shall determine eligibility for pilot programs under subsection (b).

(d) Emergency declaration defined

For purposes of this section, the term “emergency declaration” means a declaration of a public health emergency under section 9604(a) of this title.

(e) Environmental exposure affected individual defined

(1) In general

For purposes of this section, the term “environmental exposure affected individual” means—

(A) an individual described in paragraph (2); and

(B) an individual described in paragraph (3).

(2) Individual described

(A) In general

An individual described in this paragraph is any individual who—

(i) is diagnosed with 1 or more conditions described in subparagraph (B); and

(ii) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6 months in the geographic area subject to an emergency declaration specified in subsection (b)(2)(A), during a period ending—

(I) not less than 10 years prior to such diagnosis; and

(II) prior to the implementation of all the remedial and removal actions specified in the Record of Decision for Operating Unit 4 and the Record of Decision for Operating Unit 7;

(iii) files an application for benefits under this subchapter (or has an application filed on behalf of the individual), including pursuant to this section; and

(iv) is determined under this section to meet the criteria in this subparagraph.

(B) Conditions described

For purposes of subparagraph (A), the following conditions are described in this subparagraph:

(i) Asbestosis, pleural thickening, or pleural plaques as established by—

(I) interpretation by a “B Reader” qualified physician of a plain chest x-ray or interpretation of a computed tomographic radiograph of the chest by a qualified physician, as determined by the Secretary; or

(II) such other diagnostic standards as the Secretary specifies,

except that this clause shall not apply to pleural thickening or pleural plaques unless there are symptoms or conditions requiring medical treatment as a result of these diagnoses.
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(ii) Mesothelioma, or malignancies of the lung, colon, rectum, larynx, stomach, esophagus, pharynx, or ovary, as established by—

(I) pathologic examination of biopsy tissue;

(ii) cytology from bronchoalveolar lavage; or

(iii) such other diagnostic standards as the Secretary specifies.

(iii) Any other diagnosis which the Secretary, in consultation with the Commissioner of Social Security, determines is an asbestos-related medical condition, as established by such diagnostic standards as the Secretary specifies.

(3) Other individual described

An individual described in this paragraph is any individual who—

(A) is not an individual described in paragraph (2);

(B) is diagnosed with a medical condition caused by the exposure of the individual to a public health hazard to which an emergency declaration applies, based on such medical conditions, diagnostic standards, and other criteria as the Secretary specifies;

(C) as demonstrated in such manner as the Secretary determines appropriate, has been present for an aggregate total of 6 months in the geographic area subject to the emergency declaration involved, during a period determined appropriate by the Secretary;

(D) files an application for benefits under this subchapter (or has an application filed on behalf of the individual), including pursuant to this section; and

(E) is determined under this section to meet the criteria in this paragraph.


REFERENCES IN TEXT

Parts A and B, referred to in subsecs. (a)(3) and (b)(2), are classified to sections 1395c et seq. and 1395j et seq., respectively, of this title.

§ 1395ss. Certification of medicare supplemental health insurance policies

(a) Submission of policy by insurer

(1) The Secretary shall establish a procedure whereby medicare supplemental policies (as defined in subsection (g)(1) of this section) may be certified by the Secretary as meeting minimum standards and requirements set forth in subsection (c) of this section. Such procedure shall provide an opportunity for any insurer to submit any such policy, and such additional data as the Secretary finds necessary, to the Secretary for his examination and for his certification thereof as meeting the standards and requirements set forth in subsection (c) of this section. Subject to subsections (k)(9), (m), and (n) of this section, such certification shall remain in effect if the insurer files a notarized statement with the Secretary no later than June 30 of each year stating that the policy continues to meet such standards and requirements and if the insurer submits such additional data as the Secretary finds necessary to independently verify the accuracy of such notarized statement. Where the Secretary determines such a policy meets (or continues to meet) such standards and requirements, he shall authorize the insurer to have printed on such policy (but only in accordance with such requirements and conditions as the Secretary may prescribe) an emblem which the Secretary shall cause to be designed for use as an indication that a policy has received the Secretary’s certification. The Secretary shall provide each State commissioner or superintendent of insurance with a list of all the policies which have received his certification.

(2) No medicare supplemental policy may be issued in a State on or after the date specified in subsection (p)(1)(C) of this section unless—

(A) the State’s regulatory program under subsection (b)(1) of this section provides for the application and enforcement of the standards and requirements set forth in such subsection (including the 1991 NAIC Model Regulation or 1991 Federal Regulation (as the case may be)) by the date specified in subsection (p)(1)(C) of this section; or

(B) if the State’s program does not provide for the application and enforcement of such standards and requirements, the policy has been certified by the Secretary under paragraph (1) as meeting the standards and requirements set forth in subsection (c) of this section (including such applicable standards) by such date.

Any person who issues a medicare supplemental policy, on and after the effective date specified in subsection (p)(1)(C) of this section, in violation of this paragraph is subject to a civil money penalty of not to exceed $25,000 for each such violation. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(b) Standards and requirements; periodic review by Secretary

(1) Any medicare supplemental policy issued in any State in which the Secretary determines has established under State law a regulatory program that—

(A) provides for the application and enforcement of standards with respect to such policies equal to or more stringent than the NAIC Model Standards (as defined in subsection (g)(2)(A) of this section), except as otherwise provided provided by subparagraph (H);

(B) includes requirements equal to or more stringent than the requirements described in paragraphs (2) through (5) of subsection (c) of this section;

(C) provides that—

(i) information with respect to the actual ratio of benefits provided to premiums collected under such policies will be reported to the State on forms conforming to those developed by the National Association of Insurance Commissioners for such purpose, or

(ii) such ratios will be monitored under the program in an alternative manner approved...
by the Secretary, and that a copy of each such policy, the most recent premium for each such policy, and a listing of the ratio of benefits provided to premiums collected for the most recent 3-year period for each such policy issued or sold in the State is maintained and made available to interested persons;

(D) provides for application and enforcement of the standards and requirements described in subparagraphs (A), (B), and (C) to all medicare supplemental policies (as defined in subsection (g)(1) of this section) issued in such State,

(E) provides the Secretary periodically (but at least annually) with a list containing the name and address of the issuer of each such policy and the name and number of each such policy (including an indication of policies that have been previously approved, newly approved, or withdrawn from approval since the previous list was provided),

(F) reports to the Secretary on the implementation and enforcement of standards and requirements of this paragraph at intervals established by the Secretary,

(G) provides for a process for approving or disapproving proposed premium increases with respect to such policies, and establishes a policy for the holding of public hearings prior to approval of a premium increase, and

(H) in the case of a policy that meets the standards under subparagraph (A) except that benefits under the policy are limited to items and services furnished by certain entities (reduced benefits are provided when items or services are furnished by other entities), provides for the application of requirements equal to or more stringent than the requirements under subsection (t) of this section,

shall be deemed (subject to subsections (k)(3), (m), and (n) of this section, for so long as the Secretary finds that such State regulatory program continues to meet the standards and requirements of this paragraph) to meet the standards and requirements set forth in subsection (c) of this section. Each report required under subparagraph (F) shall include information on loss ratios of policies sold in the State, frequency and types of instances in which policies approved by the State fail to meet the standards and requirements of this paragraph, actions taken by the State to bring such policies into compliance, information regarding State programs implementing consumer protection provisions, and such further information as the Secretary in consultation with the National Association of Insurance Commissioners may specify.

(2) The Secretary periodically shall review State regulatory programs to determine if they continue to meet the standards and requirements specified in paragraph (1). If the Secretary finds that a State regulatory program no longer meets the standards and requirements, before making a final determination, the Secretary shall provide the State an opportunity to adopt such a plan of correction as would permit the State regulatory program to continue to meet such standards and requirements. If the Secretary makes a final determination that the State regulatory program, after such an opportunity, fails to meet such standards and requirements, the program shall no longer be considered to have in operation a program meeting such standards and requirements.

(3) Notwithstanding paragraph (1), a medicare supplemental policy offered in a State shall not be deemed to meet the standards and requirements set forth in subsection (c) of this section, with respect to an advertisement (whether through written, radio, or television medium) used (or, at a State’s option, to be used) for the policy in the State, unless the entity issuing the policy provides a copy of each advertisement to the Commissioner of Insurance (or comparable officer identified by the Secretary) of that State for review or approval to the extent it may be required under State law.

(c) Requisite findings

The Secretary shall certify under this section any medicare supplemental policy, or continue certification of such a policy, only if he finds that such policy (or, with respect to paragraph (3) or the requirement described in subsection (a) of this section, the issuer of the policy)—

(1) meets or exceeds (either in a single policy or, in the case of nonprofit hospital and medical service associations, in one or more policies issued in conjunction with one another) the NAIC Model Standards (except as otherwise provided by subsection (t) of this section);

(2) meets the requirements of subsection (r) of this section;

(3)(A) accepts a notice under section 1395u(h)(3)(B) of this title as a claim form for benefits under such policy in lieu of any claim form otherwise required and agrees to make a payment determination on the basis of the information contained in such notice;

(B) where such a notice is received—

(1) provides notice to such physician or supplier and the beneficiary of the payment determination under the policy, and

(2) provides any payment covered by such policy directly to the participating physician or supplier involved;

(C) provides each enrollee at the time of enrollment a card listing the policy name and number and a single mailing address to which notices under section 1395u(h)(3)(B) of this title respecting the policy are to be sent;

(D) agrees to pay any user fees established under section 1395u(h)(3)(B) of this title with respect to information transmitted to the issuer of the policy; and

(E) provides to the Secretary at least annually, for transmittal to carriers, a single mailing address to which notices under section 1395u(h)(3)(B) of this title respecting the policy are to be sent;

(4) may, during a period of not less than 30 days after the policy is issued, be refunded for a full refund of any premiums paid (without regard to the manner in which the purchase of the policy was solicited); and

(5) meets the applicable requirements of subsections (o) through (t) of this section.
(d) Criminal penalties; civil penalties for certain violations

(1) Whoever knowingly and willfully makes or causes to be made or induces or seeks to induce the making of any false statement or representation of a material fact with respect to the compliance of any policy with the standards and requirements set forth in subsection (c) of this section or in regulations promulgated pursuant to such subsection, or with respect to the use of the emblem designed by the Secretary under subsection (a) of this section, shall be fined under title 18 or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $5,000 for each such prohibited act.

(2) Whoever falsely assumes or pretends to be acting, or misrepresents in any way that he is acting, under the authority of or in association with, the program of health insurance established by this subchapter, or any Federal agency, for the purpose of selling or attempting to sell insurance, or in such pretended character demands, or obtains money, paper, documents, or anything of value, shall be fined under title 18 or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $5,000 for each such prohibited act.

(3)(A)(i) It is unlawful for a person to sell or issue to an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter (including an individual electing a Medicare+Choice plan under section 1395w–21 of this title)—

(I) a health insurance policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under this subchapter or subchapter XIX of this chapter,

(II) in the case of an individual not electing a Medicare+Choice plan, a Medicare supplemental policy with knowledge that the individual is entitled to benefits under another medicare supplemental policy or in the case of an individual electing a Medicare+Choice plan, a medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Medicare+Choice plan or under another medicare supplemental policy, or

(III) a health insurance policy (other than a Medicare supplemental policy) with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled, other than benefits to which the individual is entitled under a requirement of State or Federal law.

(ii) Whoever violates clause (i) shall be fined under title 18 or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $25,000 (or $15,000 in the case of a person other than the issuer of the policy) for each such prohibited act.

(iii) A seller (who is not the issuer of a health insurance policy) shall not be considered to violate clause (i)(II) with respect to the sale of a medicare supplemental policy if the policy is sold in compliance with subparagraph (B).

(iv) For purposes of this subparagraph, a health insurance policy (other than a Medicare supplemental policy) providing for benefits which are payable to or on behalf of an individual without regard to other health benefit coverage of such individual is not considered to “duplicate” any health benefits under this subchapter, under subchapter XIX of this chapter, or under a health insurance policy, and subclauses (I) and (III) of clause (i) do not apply to such a policy.

(v) For purposes of this subparagraph, a health insurance policy (or a rider to an insurance contract which is not a health insurance policy) is not considered to “duplicate” health benefits under this subchapter or under another health insurance policy if it—

(I) provides health care benefits only for long-term care, nursing home care, home health care, or community-based care, or any combination thereof,

(II) coordinates against or excludes items and services available or paid for under this subchapter or another health insurance policy, and

(III) for policies sold or issued on or after the end of the 90-day period beginning on August 21, 1996, discloses such coordination or exclusion in the policy’s outline of coverage.

For purposes of this clause, the terms “coordinates” and “coordination” mean, with respect to a policy in relation to health benefits under this subchapter or another health insurance policy, that the policy under its terms is secondary to, or excludes from payment, items and services to the extent available or paid for under this subchapter or another health insurance policy.

(vi)(I) An individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter who is applying for a health insurance policy (other than a policy described in subclause (III)) to an individual described in subclause (III) shall be furnished a disclosure statement described in clause (vii) for the type of policy being applied for. Such statement shall be furnished as a part of (or together with) the application for such policy.

(II) Whoever issues or sells a health insurance policy (other than a policy described in subclause (III)) to an individual described in subclause (I) and fails to furnish the appropriate disclosure statement as required under such subclause shall be fined under title 18, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $25,000 (or $15,000 in the case of a person other than the issuer of the policy) for each such violation.

(III) A policy described in this subclause (to which subclauses (I) and (II) do not apply) is a Medicare supplemental policy, a policy described in clause (v), or a health insurance policy identified under 60 Federal Register 30880 (June 12, 1995) as a policy not required to have a disclosure statement.

(IV) Any reference in this section to the revised NAIC model regulation (referred to in subsection (m)(1)(A) of this section) is deemed a reference to such regulation as revised by section 171(m)(2) of the Social Security Act Amend-
ments of 1994 (Public Law 103–423) and as modified by substituting, for the disclosure required under section 16D(2), disclosure under subclause (I) of an appropriate disclosure statement under clause (vii).

(vi) The disclosure statement described in this clause for a type of policy is the statement specified under subparagraph (D) of this paragraph (as in effect before August 21, 1996) for that type of policy, as revised as follows:

(I) in each statement, amend the second line to read as follows:

"THIS IS NOT MEDICARE SUPPLEMENT INSURANCE."

(II) in each statement, strike the third line and insert the following: "Some health care services paid for by Medicare may also trigger the payment of benefits under this policy."

(III) in each statement not described in subclause (V), strike the boldface matter that begins "This insurance" and all that follows up to the next paragraph that begins "Medicare".

(IV) in each statement not described in subclause (V), insert before the boxed matter (that states "BEFORE YOU BUY THIS INSURANCE") the following: "This policy must pay benefits without regard to other health benefit coverage to which you may be entitled under Medicare or other insurance."

(V) in a statement relating to policies providing both nursing home and non-institutional coverage, to policies providing nursing home benefits only, or policies providing home care benefits only, amend the sentence that begins "Federal law" to read as follows: "Federal law requires us to inform you that in certain situations this insurance may pay for some care also covered by Medicare."

(viii)(I) Subject to subclause (II), nothing in this subparagraph shall restrict or preclude a State’s ability to regulate health insurance policies, including any health insurance policy that is described in clause (iv), (v), or (vi)(III).

(II) A State may not declare or specify, in statute, regulation, or otherwise, that a health insurance policy (other than a Medicare supplemental policy) or rider to an insurance contract which is not a health insurance policy, that is described in clause (iv), (v), or (vi)(III) and that is sold, issued, or renewed to an individual entitled to benefits under part A of this subchapter or under a Medicare supplemental policy.

(B)(i) It is unlawful for a person to issue or sell a Medicare supplemental policy to an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, whether directly, through the mail, or otherwise, unless—

(I) the person obtains from the individual, as part of the application for the issuance or purchase and on a form described in clause (ii), a written statement signed by the individual stating, to the best of the individual’s knowledge, that health insurance policies (including any Medicare+Choice plan) the individual has, from what source, and whether the individual is entitled to any medical assistance under subchapter XIX of this chapter, whether as a qualified medicare beneficiary or otherwise, and

(II) the written statement is accompanied by a written acknowledgment, signed by the seller of the policy, of the request for and receipt of such statement.

(ii) The statement required by clause (i) shall be made on a form that—

(I) states in substance that a medicare-eligible individual does not need more than one medicare supplemental policy,

(II) states in substance that individuals may be eligible for benefits under the State medical aid program under subchapter XIX of this chapter and that such individuals who are entitled to benefits under that program usually do not need a medicare supplemental policy and that benefits and premiums under any such policy shall be suspended upon request of the policyholder during the period (of not longer than 24 months) of entitlement to benefits under such subchapter and may be reinstituted upon loss of such entitlement, and

(III) states that counseling services may be available in the State to provide advice concerning the purchase of medicare supplemental policies and enrollment under the medicaid program and may provide the telephone number for such services.

(iii)(I) Except as provided in subclauses (II) and (III), if the statement required by clause (i) is not obtained or indicates that the individual has a medicare supplemental policy or indicates that the individual is entitled to any medical assistance under subchapter XIX of this chapter, the sale of a medicare supplemental policy shall be considered to be a violation of subparagraph (A).

(II) Subclause (I) shall not apply in the case of an individual who has a medicare supplemental policy, if the individual indicates in writing, as part of the application for purchase, that the policy being purchased replaces such other policy and indicates an intent to terminate the policy being replaced when the new policy becomes effective and the issuer or seller certifies in writing that such policy will not, to the best of the issuer’s or seller’s knowledge, duplicate coverage (taking into account any such replacement).

(III) If the statement required by clause (i) is obtained and indicates that the individual is entitled to any medical assistance under subchapter XIX of this chapter, the sale of the policy is not in violation of clause (i) (insofar as such clause relates to such medical assistance), if (aa) a State medicaid plan under such subchapter pays the premiums for the policy, (bb) in the case of a qualified medicare beneficiary described in section 1396d(p)(1) of this title, the policy provides for coverage of outpatient prescription drugs, or (cc) the only medical assistance to which the individual is entitled under the State plan is medicare cost sharing described in section 1396d(p)(3)(A) of this title.

(iv) Whoever issues or sells a Medicare supplemental policy in violation of this subparagraph shall be fined under title 18, or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject
to a civil money penalty of not to exceed $25,000 (or $15,000 in the case of a seller who is not the issuer of a policy) for each such violation.

(C) Subparagraph (A) shall not apply with respect to the sale or issuance of a group policy or plan of one or more employers or labor organizations, or of the trustees of a fund established by one or more employers or labor organizations (or combination thereof), for employees or former employees (or combination thereof) or for members or former members (or combination thereof) of the labor organizations.

(4)(A) Whoever knowingly, directly or through his agent, mails or causes to be mailed any matter for a prohibited purpose (as determined under subparagraph (B)) shall be fined under title 18 or imprisoned not more than 5 years, or both, and, in addition to or in lieu of such a criminal penalty, is subject to a civil money penalty of not to exceed $5,000 for each such prohibited act.

(B) For purposes of subparagraph (A), a prohibited purpose means the advertising, solicitation, or offer for sale of a medicare supplemental policy, or the delivery of such a policy, in or into any State in which such policy has not been approved by the State commissioner or superintendent of insurance.

(C) Subparagraph (A) shall not apply in the case of a person who mails or causes to be mailed a medicare supplemental policy into a State if such person has ascertained that the party insured under such policy to whom (or on whose behalf) such policy is mailed is located in such State on a temporary basis.

(D) Subparagraph (A) shall not apply in the case of a person who mails or causes to be mailed a duplicate copy of a medicare supplemental policy previously issued to the party to whom (or on whose behalf) such duplicate copy is mailed.

(E) Subparagraph (A) shall not apply in the case of an issuer who mails or causes to be mailed a policy, certificate, or other matter solely to comply with the requirements of subsection (q) of this section.

(5) The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under paragraphs (1), (2), (3)(A), and (4)(A) in the same manner as such provisions apply to penalties and proceedings under section 1320a–7a(a) of this title.

(e) Dissemination of information

(1) The Secretary shall provide to all individuals entitled to benefits under this subchapter (and, to the extent feasible, to individuals about to become so entitled) such information as will permit such individuals to evaluate the value of medicare supplemental policies to them and the relationship of any such policies to benefits provided under this subchapter.

(2) The Secretary shall—

(A) inform all individuals entitled to benefits under this subchapter (and, to the extent feasible, individuals about to become so entitled) of—

(i) the actions and practices that are subject to sanctions under subsection (d) of this section, and

(ii) the manner in which they may report any such action or practice to an appropriate official of the Department of Health and Human Services (or to an appropriate State official), and

(B) publish the toll-free telephone number for individuals to report suspected violations of the provisions of such subsection.

(3) The Secretary shall provide individuals entitled to benefits under this subchapter (and, to the extent feasible, individuals about to become so entitled) with a listing of the addresses and telephone numbers of State and Federal agencies and offices that provide information and assistance to individuals with respect to the selection of medicare supplemental policies.

(f) Study and evaluation of comparative effectiveness of various State approaches to regulating medicare supplemental policies; report to Congress no later than January 1, 1982; periodic evaluations

(1)(A) The Secretary shall, in consultation with Federal and State regulatory agencies, the National Association of Insurance Commissioners, private insurers, and organizations representing consumers and the aged, conduct a comprehensive study and evaluation of the comparative effectiveness of various State approaches to the regulation of medicare supplemental policies in (i) limiting marketing and agent abuse, (ii) assuring the dissemination of such information to individuals entitled to benefits under this subchapter (and to other consumers) as is necessary to permit informed choice, (iii) promoting policies which provide reasonable economic benefits for such individuals, (iv) reducing the purchase of unnecessary duplicative coverage, (v) improving price competition, and (vi) establishing effective approved State regulatory programs described in subsection (b) of this section.

(B) Such study shall also address the need for standards or certification of health insurance policies, other than medicare supplemental policies, sold to individuals eligible for benefits under this subchapter.

(C) The Secretary shall, no later than January 1, 1982, submit a report to the Congress on the results of such study and evaluation, accompanied by such recommendations as the Secretary finds warranted by such results with respect to the need for legislative or administrative changes to accomplish the objectives set forth in subparagraphs (A) and (B), including the need for a mandatory Federal regulatory program to assure the marketing of appropriate types of medicare supplemental policies, and such other means as he finds may be appropriate to enhance effective State regulation of such policies.

(2) The Secretary shall submit to the Congress no later than July 1, 1982, and periodically as may be appropriate thereafter (but not less often than once every 2 years), a report evaluating the effectiveness of the certification procedure and the criminal penalties established under this section, and shall include in such reports an analysis of—

(A) the impact of such procedure and penalties on the types, market share, value, and cost to individuals entitled to benefits under
this subchapter of medicare supplemental policies which have been certified by the Secretary;

(B) the need for any change in the certification procedure to improve its administration or effectiveness; and

(C) whether the certification program and criminal penalties should be continued.

(3) The Secretary shall provide information via a toll-free telephone number on medicare supplemental policies (including the relationship of State programs under subchapter XIX of this chapter to such policies).

(g) Definitions

(1) For purposes of this section, a medicare supplemental policy is a health insurance policy or other health benefit plan offered by a private entity to individuals who are entitled to have payment made under this subchapter, which provides for reimbursement for expenses incurred for services and items for which payment may be made under this subchapter but which are not reimbursable by reason of the applicability of deductibles, coinsurance amounts, or other limitations imposed pursuant to this subchapter; but does not include a prescription drug plan under part D of this subchapter or a Medicare+Choice plan or any such policy or plan of one or more employers or labor organizations, or of the trustees of a fund established by one or more employers or labor organizations (or combination thereof), for employees or former employees (or combination thereof) of the labor organizations and does not include a policy or plan of an eligible organization (as defined in section 1395mm(b) of this title) if the policy or plan provides benefits pursuant to a contract under section 1395mm of this title or an approved demonstration project described in section 603(c) of the Social Security Amendments of 1993, section 2355 of the Deficit Reduction Act of 1984, or section 112(b) of the Omnibus Budget Reconciliation Act of 1986, or a policy or plan of an organization if the policy or plan provides benefits pursuant to an agreement under section 1395(a)(1)(A) of this title. For purposes of this section, the term “policy” includes a certificate issued under such policy.

(2) For purposes of this section:

(A) The term “NAIC Model Standards” means the “NAIC Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act”, adopted by the National Association of Insurance Commissioners on June 6, 1979, as it applies to medicare supplemental policies.

(B) The term “State with an approved regulatory program” means a State for which the Secretary has made a determination under subsection (b)(1) of this section.

(C) The State in which a policy is issued means—

(i) in the case of an individual policy, the State in which the policyholder resides; and

(ii) in the case of a group policy, the State in which the holder of the master policy resides.

(h) Rules and regulations

The Secretary shall prescribe such regulations as may be necessary for the effective, efficient, and equitable administration of the certification procedure established under this section. The Secretary shall first issue final regulations to implement the certification procedure established under subsection (a) of this section not later than March 1, 1981.

(i) Commencement of certification program

(1) No medicare supplemental policy shall be certified and no such policy may be issued bearing the emblem authorized by the Secretary under subsection (a) of this section until July 1, 1982. On and after such date policies certified by the Secretary may bear such emblem, including policies which were issued prior to such date and were subsequently certified, and insurers may notify holders of such certified policies issued prior to such date using such emblem in the notification.

(2)(A) The Secretary shall not implement the certification program established under subsection (a) of this section with respect to policies issued in a State unless the Panel makes a finding that such State cannot be expected to have established, by July 1, 1982, an approved State regulatory program meeting the standards and requirements of subsection (b)(1) of this section. If the Panel makes such a finding, the Secretary shall implement such program under subsection (a) of this section with respect to medicare supplemental policies issued in such State, until such time as the Panel determines that such State has a program that meets the standards and requirements of subsection (b)(1) of this section.

(B) Any finding by the Panel under subparagraph (A) shall be transmitted in writing, not later than January 1, 1982, to the Committee on Finance of the Senate and to the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives and shall not become effective until 60 days after the date of its transmittal to the Committees of the Congress under this subparagraph. In counting such days, days on which either House is not in session because of an adjournment sine die or an adjournment of more than three days to a day certain are excluded in the computation.

(j) State regulation of policies issued in other States

Nothing in this section shall be construed so as to affect the right of any State to regulate medicare supplemental policies which, under the provisions of this section, are considered to be issued in another State.

(k) Amended NAIC Model Regulation or Federal model standards applicable; effective date; medicare supplemental policy and State regulatory program meeting applicable standards

(1)(A) If, within the 90-day period beginning on July 1, 1988, the National Association of Insurance Commissioners (in this subsection referred to as the “Association”) amends the NAIC Model Regulation adopted on June 6, 1979 (as it relates to medicare supplemental policies), with respect to matters such as minimum benefit standards, loss ratios, disclosure requirements, and replacement requirements and provisions
otherwise necessary to reflect the changes in law made by the Medicare Catastrophic Coverage Act of 1988, except as provided in subsection (m) of this section, subsection (g)(2)(A) of this section shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the Model Regulation as amended by the Association in accordance with this paragraph (in this subsection and subsection (i) of this section referred to as the “amended NAIC Model Regulation”).

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the amended NAIC Model Regulation or 1 year after the date the Association first adopts such amended Regulation.

(2)(A) If the Association does not amend the NAIC Model Regulation within the 90-day period specified in paragraph (1)(A), the Secretary shall promulgate, not later than 60 days after the end of such period, Federal model standards (in this subsection and subsection (i) of this section referred to as “Federal model standards”) for medicare supplemental policies to reflect the changes in law made by the Medicare Catastrophic Coverage Act of 1988, and subsection (g)(2)(A) of this section shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to Federal model standards.

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the Federal model standards or 1 year after the date the Secretary first promulgates such standards.

(3) Notwithstanding any other provision of this section (except as provided in subsections (i), (m), and (n) of this section)—

(A) no medicare supplemental policy may be certified by the Secretary pursuant to subsection (a) of this section,

(B) no certification made pursuant to subsection (a) of this section shall remain in effect, and

(C) no State regulatory program shall be found to meet (or to continue to meet) the requirements of subsection (b)(1)(A) of this section, unless such policy meets (or such program provides for the application of standards equal to or more stringent than) the standards set forth in the amended NAIC Model Regulation or the Federal model standards (as the case may be) by the date specified in paragraph (1)(B) or (2)(B) (as the case may be).

(l) Transitional compliance with NAIC Model Transition Regulation; “qualifying medicare supplemental policy” and “NAIC Model Transition Regulation” defined

(1) Until the date specified in paragraph (3), in the case of a qualifying medicare supplemental policy described in paragraph (2) issued—

(A) before January 1, 1989, the policy is deemed to remain in compliance with this section if the insurer issuing the policy complies with the NAIC Model Transition Regulation (including giving notices to subscribers and filing for premium adjustments with the State as described in section 5.B. of such Regulation) by January 1, 1989; or

(B) on or after January 1, 1989, the policy is deemed to be in compliance with this section if the insurer issuing the policy complies with the NAIC Model Transition Regulation before the date of the sale of the policy.

(2) In paragraph (1), the term “qualifying medicare supplemental policy” means a medicare supplemental policy—

(A) issued in a State which—

(i) has not adopted standards equal to or more stringent than the NAIC Model Transition Regulation by January 1, 1989, and

(ii) has not adopted standards equal to or more stringent than the amended NAIC Model Regulation (or Federal model standards) by January 1, 1989; and

(B) which has been issued in compliance with this section (as in effect on June 1, 1988).

(3)(A) The date specified in this paragraph is the earlier of—

(i) the first date a State adopts, after January 1, 1989, standards equal to or more stringent than the NAIC Model Transition Regulation or equal to or more stringent than the amended NAIC Model Regulation (or Federal model standards), as the case may be, or

(ii) the later of (I) the date specified in subsection (k)(1)(B) or (k)(2)(B) of this section (as the case may be), or (II) the date specified in subparagraph (B).

(B) In the case of a State which the Secretary identifies as—

(i) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to meet standards described in subparagraph (A)(i), but

(ii) having a legislature which is not scheduled to meet in 1989 in a legislative session in which such legislation may be considered, the date specified in this subparagraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1989, and in which legislation described in clause (i) may be considered. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(4) In the case of a medicare supplemental policy in effect on January 1, 1989, and offered in a State which, as of such date—

(A) has adopted standards equal to or more stringent than the amended NAIC Model Regulation (or Federal model standards), but

(B) does not have in effect standards equal to or more stringent than the NAIC Model Transition Regulation (or otherwise requiring notice substantially the same as the notice required in section 5.B. of such Regulation), the policy shall not be deemed to meet the standards in subsection (c) of this section unless each individual who is entitled to benefits under
this subchapter and is a policyholder under such policy on January 1, 1989, is sent such a notice in any appropriate form by not later than January 31, 1989, that explains—

(A) the improved benefits under this subchapter contained in the Medicare Catastrophic Coverage Act of 1988, and

(B) how these improvements affect the benefits contained in the policies and the premium for the policy.

(5) In this subsection, the term “NAIC Model Transition Regulation” refers to the standards contained in the “Model Regulation to Implement Transitional Requirements for the Conversion of Medicare Supplement Insurance Benefits and Premiums to Conform to Medicare Program Revisions” (as adopted by the National Association of Insurance Commissioners in September 1987).

(m) Revision of amended NAIC Model Regulation and amended Federal model standards; effective dates; medicare supplemental policy and State regulatory program meeting applicable standards

(1)(A) If, within the 90-day period beginning on December 13, 1989, the National Association of Insurance Commissioners (in this subsection and subsection (n) of this section referred to as the “Association”) revises the amended NAIC Model Regulation (referred to in subsection (k)(1)(A) of this section and adopted on September 20, 1988) to improve such regulation and otherwise to reflect the changes in law made by the Medicare Catastrophic Coverage Repeal Act of 1989, subsection (g)(2)(A) of this section shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised Federal model standards’’ (as the case may be).

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the revised Federal model standards or 1 year after the date the Federal model standards were a reference to the revised Federal model standards.

(C) The date specified in this subparagraph for a State—

(A) no medicare supplemental policy may be certified by the Secretary pursuant to subsection (a) of this section,

(B) no certification made pursuant to subsection (a) of this section shall remain in effect, and

(C) no State regulatory program shall be found to meet (or to continue to meet) the requirements of subsection (b)(1)(A) of this section, unless such policy meets (or such program provides for the application of standards equal to or more stringent than) the standards set forth in the revised NAIC Model Regulation or the revised Federal model standards (as the case may be).

(n) Transition compliance with revision of NAIC Model Regulation and Federal model standards

(1) Until the date specified in paragraph (4), in the case of a qualifying medicare supplemental policy described in paragraph (3) issued in a State—

(A) before the transition deadline, the policy is deemed to be in compliance with the standards described in subsection (b)(1)(A) of this section only if the insurer issuing the policy complies with the transition provision described in paragraph (2), or

(B) on or after the transition deadline, the policy complies with the standards described in subsection (b)(1)(A) of this section only if the insurer issuing the policy complies with the revised NAIC Model Regulation or the revised Federal model standards (as the case may be) before the date of sale of the policy.

In this paragraph, the term “transition deadline” means 1 year after the date the Association first adopts the revised NAIC Model Regulation or 1 year after the date the Secretary promulgates revised Federal model standards (as the case may be).

(2) The transition provision described in this paragraph is—

(A) such transition provision as the Association provides, by not later than December 15, 1989, so as to provide for an appropriate transition (i) to restore benefit provisions which are no longer duplicative as a result of the changes in benefits under this subchapter contained in the Medicare Catastrophic Coverage Repeal Act of 1989, subsection (g)(2)(A) of this section shall be applied in a State, effective on and after the date specified in subparagraph (B), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised Federal model standards.

(B) The date specified in this subparagraph for a State is the earlier of the date the State adopts standards equal to or more stringent than the revised Federal model standards or 1 year after the date the Secretary first promulgates such standards.

(3) Notwithstanding any other provision of this section (except as provided in subsection (n) of this section)—

(A) no medicare supplemental policy may be certified by the Secretary pursuant to subsection (a) of this section,

(B) no certification made pursuant to subsection (a) of this section shall remain in effect, and

(C) no State regulatory program shall be found to meet (or to continue to meet) the requirements of subsection (b)(1)(A) of this section, unless such policy meets (or such program provides for the application of standards equal to or more stringent than) the standards set forth in the revised NAIC Model Regulation or the revised Federal model standards (as the case may be).
care supplemental policy which has been issued in compliance with this section as in effect on the date before December 13, 1989.

(4)(A) The date specified in this paragraph for a policy issued in a State is—

(i) the first date a State adopts, after December 13, 1989, standards equal to or more stringent than the revised NAIC Model Regulation (or revised Federal model standards), as the case may be, or

(ii) the date specified in subparagraph (B), whichever is earlier.

(B) In the case of a State which the Secretary identifies, in consultation with the Association, as—

(i) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to meet standards described in subparagraph (A)(i), but

(ii) having a legislature which is not scheduled to meet in 1990 in a legislative session in which such legislation may be considered,

the date specified in this subparagraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1990. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(5) In the case of a medicare supplemental policy in effect on January 1, 1990, the policy shall not be deemed to meet the standards in subsection (c) of this section unless each individual who is entitled to benefits under this subchapter and is a policyholder or certificate holder under such policy on such date is sent a notice in an appropriate form by not later than January 31, 1990, that explains—

(A) the changes in benefits under this subchapter effected by the Medicare Catastrophic Coverage Repeal Act of 1989, and

(B) how these changes may affect the benefits contained in such policy and the premium for the policy.

(6)(A) Except as provided in subparagraph (B), in the case of an individual who had in effect, as of December 31, 1988, a medicare supplemental policy with an insurer (as a policyholder or, in the case of a group policy, a certificate holder) and the individual terminated coverage under such policy before December 13, 1989, no medicare supplemental policy of the insurer shall be deemed to meet the standards in subsection (c) of this section unless the insurer—

(i) provides written notice, no earlier than December 15, 1989, and no later than January 30, 1990, to the policyholder or certificate holder (at the most recent available address) of the offer described in clause (ii), and

(ii) offers the individual, during a period of at least 60 days beginning not later than February 1, 1990, reinstatement of coverage (with coverage effective as of January 1, 1990), under the terms which (I) do not provide for any waiting period with respect to treatment of pre-existing conditions, (II) provides for coverage which is substantially equivalent to coverage in effect before the date of such termi-

nation, and (III) provides for classification of premiums on which terms are at least as favorable to the policyholder or certificate holder as the premium classification terms that would have applied to the policyholder or certificate holder had the coverage never terminated.

(B) An insurer is not required to make the offer under subparagraph (A)(ii) in the case of an individual who is a policyholder or certificate holder in another medicare supplemental policy as of December 13, 1989, if (as of January 1, 1990) the individual is not subject to a waiting period with respect to treatment of a pre-existing condition under such other policy.

(o) Requirements of group benefits; core group benefits; uniform outline of coverage

The requirements of this subsection are as follows:

(1) Each medicare supplemental policy shall provide for coverage of a group of benefits consistent with subsections (p), (v)\(^1\) (w), and (y) of this section.

(2) If the medicare supplemental policy provides for coverage of a group of benefits other than the core group of basic benefits described in subsection (p)(2)(B) of this section, the issuer of the policy must make available to the individual a medicare supplemental policy with only such core group of basic benefits.

(3) The issuer of the policy has provided, before the sale of the policy, an outline of coverage that uses uniform language and format (including layout and print size) that facilitates comparison among medicare supplemental policies and comparison with medicare benefits.

(4) The issuer of the medicare supplemental policy complies with subsection (s)(2)(E) and subsection (x).

(5) In addition to the requirement under paragraph (2), the issuer of the policy must make available to the individual at least medicare supplemental policies with benefit packages classified as “C” or “F”.

(p) Standards for group benefits

(1)(A) If, within 9 months after November 5, 1990, the National Association of Insurance Commissioners (in this subsection referred to as the “Association”) changes the revised NAIC Model Regulation (described in subsection (m) of this section) to incorporate—

(i) limitations on the groups or packages of benefits that may be offered under a medicare supplemental policy consistent with paragraphs (2) and (3) of this subsection,

(ii) uniform language and definitions to be used with respect to such benefits,

(iii) uniform format to be used in the policy with respect to such benefits, and

(iv) other standards to meet the additional requirements imposed by the amendments made by the Omnibus Budget Reconciliation Act of 1990,

subsection (g)(2)(A) of this section shall be applied in each State, effective for policies issued to policyholders on and after the date specified

\(^1\) So in original. Probably should be followed by a comma.
in subparagraph (C), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised NAIC Model Regulation as changed under this subparagraph (such changed regulation referred to in this section as the revised NAIC Model Regulation).

(B) If the Association does not make the changes in the revised NAIC Model Regulation within the 9-month period specified in subparagraph (A), the Secretary shall promulgate, not later than 9 months after the end of such period, a regulation and subsection (g)(2)(A) of this section shall be applied in each State, effective for policies issued to policyholders on and after the date specified in subparagraph (C), as if the reference to the Model Regulation adopted on June 6, 1979, were a reference to the revised NAIC Model Regulation as changed by the Secretary under this subparagraph (such changed regulation referred to in this section as the “1991 Federal Regulation”).

(C)(i) Subject to clause (ii), the date specified in this subparagraph for a State is the date the State adopts the 1991 NAIC Model Regulation or 1991 Federal Regulation or 1 year after the date the Association or the Secretary first adopts such standards, whichever is earlier.

(ii) In the case of a State which the Secretary identifies, in consultation with the Association, as—

(I) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to meet the 1991 NAIC Model Regulation or 1991 Federal Regulation, but

(II) having a legislature which is not scheduled to meet in 1992 in a legislative session in which such legislation may be considered,

the date specified in this subparagraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1992. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(D) In promulgating standards under this paragraph, the Association or Secretary shall consult with a working group composed of representatives of issuers of medicare supplemental policies, consumer groups, medicare beneficiaries, and other qualified individuals. Such representatives shall be selected in a manner so as to assure balanced representation among the interested groups.

(E) If benefits (including deductibles and coinsurance) under this subchapter are changed and the Secretary determines, in consultation with the Association, that changes in the 1991 NAIC Model Regulation or 1991 Federal Regulation are needed to reflect such changes, the preceding provisions of this paragraph shall apply to the modification of standards previously established in the same manner as they applied to the original establishment of such standards.

(2) The benefits under the 1991 NAIC Model Regulation or 1991 Federal Regulation shall provide—

(A) for such groups or packages of benefits as may be appropriate taking into account the considerations specified in paragraph (3) and the requirements of the succeeding subparagraphs;

(B) for identification of a core group of basic benefits common to all policies; and

(C) that, subject to paragraph (4)(B), the total number of different benefit packages (counting the core group of basic benefits described in subparagraph (B) and each other combination of benefits that may be offered as a separate benefit package) that may be established in all the States and by all issuers shall not exceed 10 plus the 2 plans described in paragraph (11)(A).

(3) The benefits under paragraph (2) shall, to the extent possible—

(A) provide for benefits that offer consumers the ability to purchase the benefits that are available in the market as of November 5, 1990; and

(B) balance the objectives of (i) simplifying the market to facilitate comparisons among policies, (ii) avoiding adverse selection, (iii) providing consumer choice, (iv) providing market stability, and (v) promoting competition.

(4)(A)(i) Except as provided in subparagraph (B) or paragraph (6), no State with a regulatory program approved under subsection (b)(1) of this section may provide for or permit the grouping of benefits (or language or format with respect to such benefits) under a medicare supplemental policy unless such grouping meets the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation.

(ii) Except as provided in subparagraph (B), the Secretary may not provide for or permit the grouping of benefits (or language or format with respect to such benefits) under a medicare supplemental policy seeking approval by the Secretary unless such grouping meets the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation.

(B) With the approval of the State (in the case of a policy issued in a State with an approved regulatory program) or the Secretary (in the case of any other policy), the issuer of a medicare supplemental policy may offer new or innovative benefits in addition to the benefits provided in a policy that otherwise complies with the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation. Any such new or innovative benefits may include benefits that are not otherwise available and are cost-effective and shall be offered in a manner which is consistent with the goal of simplification of medicare supplemental policies.

(5)(A) Except as provided in subparagraph (B), this subsection shall not be construed as preventing a State from restricting the groups of benefits that may be offered in medicare supplemental policies in the State.

(B) A State with a regulatory program approved under subsection (b)(1) of this section may not restrict under subparagraph (A) the offering of a medicare supplemental policy consisting only of the core group of benefits described in paragraph (2)(B).

(6) The Secretary may waive the application of standards described in clauses (i) through (iii) of paragraph (11)(A) in those States that on Novem-
ber 5, 1990, had in place an alternative simplification program.

(7) This subsection shall not be construed as preventing an issuer of a medicare supplemental policy who otherwise meets the requirements of this subsection from providing, through an arrangement with a vendor, for discounts from that vendor to policyholders or certificateholders for the purchase of items or services not covered under its medicare supplemental policies.

(8) Any person who sells or issues a medicare supplemental policy, on and after the effective date specified in paragraph (1)(C) (but subject to paragraph (10)), in violation of the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation insofar as such regulation relates to the requirements of subsection (o) or (q) of this section or clause (i), (ii), or (iii) of paragraph (1)(A) is subject to a civil money penalty of not to exceed $25,000 (or $15,000 in the case of a seller who is not an issuer of a policy) for each such violation. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(9)(A) Anyone who sells a medicare supplemental policy to an individual shall make available for sale to the individual a medicare supplemental policy with only the core group of basic benefits (described in paragraph (2)(B)).

(B) Anyone who sells a medicare supplemental policy to an individual shall provide the individual, before the sale of the policy, an outline of coverage which describes the benefits under the policy. Such outline shall be on a standard form approved by the State regulatory program or the Secretary (as the case may be) consistent with the 1991 NAIC Model Regulation or 1991 Federal Regulation under this subsection.

(C) Whoever sells a medicare supplemental policy in violation of this paragraph is subject to a civil money penalty of not to exceed $25,000 (or $15,000 in the case of a seller who is not the issuer of a policy) for each such violation. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(D) Subject to paragraph (10), this paragraph shall apply to sales of policies occurring on or after the effective date specified in paragraph (1)(C).

(10) No penalty may be imposed under paragraph (8) or (9) in the case of a seller who is not the issuer of a policy until the Secretary has published a list of the groups of benefit packages that may be sold or issued consistent with paragraph (1)(A)(i).

(11)(A) For purposes of paragraph (2), the benefit packages described in this subparagraph are as follows:

(i) The benefit package classified as “F” under the standards established by such paragraph, except that it has a high deductible feature.

(ii) The benefit package classified as “J” under the standards established by such paragraph, except that it has a high deductible feature.

(B) For purposes of subparagraph (A), a high deductible feature is one which—

(i) requires the beneficiary of the policy to pay annual out-of-pocket expenses (other than premiums) in the amount specified in subparagraph (C) before the policy begins payment of benefits, and

(ii) covers 100 percent of covered out-of-pocket expenses once such deductible has been satisfied in a year.

(C) The amount specified in this subparagraph—

(i) for 1998 and 1999 is $1,500, and

(ii) for a subsequent year, is the amount specified in this subparagraph for the previous year increased by the percentage increase in the Consumer Price Index for all urban consumers (all items; U.S. city average) for the 12-month period ending with August of the preceding year.

If any amount determined under clause (ii) is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(q) Guaranteed renewal of policies; termination; suspension

The requirements of this subsection are as follows:

(1) Each medicare supplemental policy shall be guaranteed renewable and—

(A) the issuer may not cancel or nonrenew the policy solely on the ground of health status of the individual; and

(B) the issuer shall not cancel or nonrenew the policy for any reason other than nonpayment of premium or material misrepresentation.

(2) If the medicare supplemental policy is terminated by the group policyholder and is not replaced as provided under paragraph (4), the issuer shall offer certificateholders an individual medicare supplemental policy which (at the option of the certificateholder)—

(A) provides for continuation of the benefits contained in the group policy, or

(B) provides for such benefits as otherwise meets the requirements of this section.

(3) If an individual is a certificateholder in a group medicare supplemental policy and the individual terminates membership in the group, the issuer shall—

(A) offer the certificateholder the conversion opportunity described in paragraph (2), or

(B) at the option of the group policyholder, offer the certificateholder continuation of coverage under the group policy.

(4) If a group medicare supplemental policy is replaced by another group medicare supplemental policy purchased by the same policyholder, issuer of the replacement policy shall offer coverage to all persons covered under the

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2So in original. Probably should be “meet”.

3So in original. Probably should be preceded by “the”. 
old group policy on its date of termination. Coverage under the new group policy shall not result in any exclusion for preexisting conditions that would have been covered under the group policy being replaced.

Each medicare supplemental policy shall provide that benefits and premiums under the policy shall be suspended at the request of the policyholder for the period (not to exceed 24 months) in which the policyholder has applied for and is determined to be entitled to medical assistance under subchapter XIX of this chapter, but only if the policyholder notifies the issuer of such policy within 90 days after the date the individual becomes entitled to such assistance. If such suspension occurs and if the policyholder or certificate holder loses entitlement to such medical assistance, such policy shall be automatically reinstated (effective as of the date of termination of such entitlement) under terms described in subsection (n)(6)(A)(ii) of this section as of the termination of such entitlement if the policyholder provides notice of loss of such entitlement within 90 days after the date of such loss.

(B) Nothing in this section shall be construed as affecting the authority of a State, under subchapter XIX of this chapter, to purchase a medicare supplemental policy for an individual otherwise entitled to assistance under such subchapter.

(C) Any person who issues a medicare supplemental policy and fails to comply with the requirements of this paragraph or paragraph (6) is subject to a civil money penalty of not to exceed $25,000 for each such violation. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

Each medicare supplemental policy shall provide that benefits and premiums under the policy shall be suspended at the request of the policyholder if the policyholder is entitled to medical assistance under section 1395y(b)(1)(A)(v) of this title. If such suspension occurs and if the policyholder or certificate holder loses coverage under the group health plan, such policy shall be automatically reinstated (effective as of the date of termination of such entitlement) under terms described in subsection (n)(6)(A)(ii) of this section as of the date of such loss if the policyholder provides notice of loss of such coverage within 90 days after the date of such loss.

(r) Required ratio of aggregate benefits to aggregate premiums

(1) A medicare supplemental policy may not be issued or renewed (or otherwise provide coverage after the date described in subsection (p)(1)(C) of this section) in any State unless—

(A) the policy can be expected for periods after the effective date of these provisions (as estimated for the entire period for which rates are computed to provide coverage, on the basis of incurred claims experience and earned premiums for such periods and in accordance with a uniform methodology, including uniform reporting standards, developed by the National Association of Insurance Commissioners) to return to policyholders in the form of aggregate benefits provided under the policy, at least 75 percent of the aggregate amount of premiums collected in the case of group policies and at least 65 percent in the case of individual policies; and

(B) the issuer of the policy provides for the issuance of a proportional refund, or a credit against future premiums of a proportional amount, based on the premium paid and in accordance with paragraph (2), of the amount of premiums received necessary to assure that the ratio of aggregate benefits provided to the aggregate premiums collected (net of such refunds or credits) complies with the expectations required under subparagraph (A), treating policies of the same type as a single policy for each standard package.

For purposes of applying subparagraph (A) only, policies issued as a result of solicitations of individuals through the mails or by mass media advertising (including both print and broadcast advertising) shall be deemed to be individual policies. For the purpose of calculating the refund or credit required under paragraph (1)(B) for a policy issued before the date specified in subsection (p)(1)(C) of this section, the refund or credit calculation shall be based on the aggregate benefits provided and premiums collected under all such policies issued by an insurer in a State (separated as to individual and group policies) and shall be based only on aggregate benefits provided and premiums collected under such policies after the date specified in section 17l(m)(4) of the Social Security Act Amendments of 1994.

(2)(A) Paragraph (1)(B) shall be applied with respect to each type of policy by standard package. Paragraph (1)(B) shall not apply to a policy until 12 months following issue. The Comptroller General, in consultation with the National Association of Insurance Commissioners, shall submit to Congress a report containing recommendations on adjustment in the percentages under paragraph (1)(A) that may be appropriate. In the case of a policy issued before the date specified in subsection (p)(1)(C) of this section, paragraph (1)(B) shall not apply until 1 year after the date specified in section 17l(m)(4) of the Social Security Act Amendments of 1994.

(B) A refund or credit required under paragraph (1)(B) shall be made to each policyholder insured under the applicable policy as of the last day of the year involved.

(C) Such a refund or credit shall include interest from the end of the calendar year involved until the date of the refund or credit at a rate as specified by the Secretary for this purpose from time to time which is not less than the average rate of interest for 13-week Treasury notes.

(D) For purposes of this paragraph and paragraph (1)(B), refunds or credits against premiums due shall be made, with respect to a calendar year, not later than the third quarter of the succeeding calendar year.
(3) The provisions of this subsection do not preempt a State from requiring a higher percentage than that specified in paragraph (1)(A).

(4) The Secretary shall submit in October of each year (beginning with 1993) a report to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate on loss ratios under medicare supplemental policies and the use of sanctions, such as a required rebate or credit or the disallowance of premium increases, for policies that fail to meet the requirements of this subsection (relating to loss ratios). Such report shall include a list of the policies that failed to comply with such loss ratio requirements or other requirements of this section.

(5) The Secretary may perform audits with respect to the compliance of medicare supplemental policies with the loss ratio requirements of this subsection and shall report the results of such audits to the State involved.

(6)(A) A person who fails to provide refunds or credits as required in paragraph (1)(B) is subject to a fine money penalty of not to exceed $25,000 for each policy issuer for which such failure occurred. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(B) Each issuer of a policy subject to the requirements of paragraph (1)(B) shall be liable to the policyholder or, in the case of a group policy, to the certificate holder for credits required under such paragraph.

(s) Coverage for pre-existing conditions

(1) If a medicare supplemental policy replaces another medicare supplemental policy, the issuer of the replacing policy shall waive any time periods applicable to preexisting conditions, waiting period, elimination periods and probationary periods in the new medicare supplemental policy for similar benefits to the extent such time was spent under the original policy.

(2)(A) The issuer of a medicare supplemental policy may not deny or condition the issuance or effectiveness of a medicare supplemental policy, or discriminate in the pricing of the policy, because of health status, claims experience, receipt of health care, or medical condition in the case of an individual for whom an application is submitted prior to or during the 6 month period beginning with the first month as of the first day on which the individual is 65 years of age or older and is enrolled for benefits under part B of this subchapter.

(B) Subject to subparagraphs (C) and (D), subparagraph (A) shall not be construed as preventing the exclusion of benefits under a policy, during its first 6 months, based on a pre-existing condition for which the policyholder received treatment or was otherwise diagnosed during the 6 months before the policy became effective.

(C) If a medicare supplemental policy or certificate replaces another such policy or certificate which has been in effect for 6 months or longer, the replacing policy may not provide any time period applicable to pre-existing conditions, waiting periods, elimination periods, and probationary periods in the new policy or certificate for similar benefits.

(D) In the case of a policy issued during the 6-month period described in subparagraph (A) to an individual who is 65 years of age or older as of the date of issuance and who as of the date of the application for enrollment has a continuous period of creditable coverage (as defined in 4 2701(c)(3) of the Public Health Service Act) of—

(i) at least 6 months, the policy may not exclude benefits based on a pre-existing condition; or

(ii) less than 6 months, if the policy excludes benefits based on a preexisting condition, the policy shall reduce the period of any preexisting condition exclusion by the aggregate of the periods of creditable coverage (if any, as so defined) applicable to the individual as of the enrollment date.

The Secretary shall specify the manner of the reduction under clause (ii), based upon the rules used by the Secretary in carrying out section 2701(a)(3) of such Act.

(E) An issuer of a medicare supplemental policy shall not deny or condition the issuance or effectiveness of the policy (including the imposition of any exclusion of benefits under the policy based on a pre-existing condition) and shall not discriminate in the pricing of the policy (including the adjustment of premium rates) of an individual on the basis of the genetic information with respect to such individual.

(F) RULE OF CONSTRUCTION.—Nothing in sub-paragraph (E) or in subparagraphs (A) or (B) of subsection (x)(2) shall be construed to limit the ability of an issuer of a medicare supplemental policy from, to the extent otherwise permitted under this subchapter—

(i) denying or conditioning the issuance or effectiveness of the policy or increasing the premium for an employer based on the manifestation of a disease or disorder of an individual who is covered under the policy; or

(ii) increasing the premium for any policy issued to an individual based on the manifestation of a disease or disorder of an individual who is covered under the policy (in such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer).

(3)(A) The issuer of a medicare supplemental policy—

(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy described in subparagraph (C) that is offered and is available for issuance to new enrollees by such issuer;

(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(iii) may not impose an exclusion of benefits based on a preexisting condition under such policy.

* So in original. Probably should be followed by "section".

* See References in Text note below.
in the case of an individual described in subparagraph (B) who seeks to enroll under the policy during the period specified in subparagraph (E) and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy. (B) An individual described in this subparagraph is an individual described in any of the following clauses:

(i) The individual is enrolled under an employee welfare benefit plan that provides health benefits that supplement the benefits under this subchapter and the plan terminates or ceases to provide all such supplemental health benefits to the individual.

(ii) The individual is enrolled with a Medicare+Choice organization under a Medicare+Choice plan under part C of this subchapter, and there are circumstances permitting discontinuance of the individual's election of the plan under the first sentence of section 1395w–21(e)(4) of this title or the individual is 65 years of age or older and is enrolled with a PACE provider under section 1395see of this title, and there are circumstances that would permit the discontinuance of the individual's enrollment with such provider under circumstances that are similar to the circumstances that would permit discontinuance of the individual's election under the first sentence of such section if such individual were enrolled in a Medicare+Choice plan.

(iii) The individual is enrolled with an eligible organization under a contract under section 1395mm of this title, a similar organization operating under demonstration project authority, effective for periods before April 1, 1999, with an organization under an agreement under section 1395f(a)(1)(A) of this title, or with an organization under a policy described in subsection (t) of this section, and such enrollment ceases under the same circumstances that would permit discontinuance of an individual's election of coverage under the first sentence of section 1395w–21(e)(4) of this title and, in the case of a policy described in subsection (t) of this section, there is no provision under applicable State law for the continuation or conversion of coverage under such policy.

(iv) The individual is enrolled under a medicare supplemental policy under this section and such enrollment ceases because

(I) of the bankruptcy or insolvency of the issuer or because of other involuntary termination of coverage or enrollment under such policy and there is no provision under applicable State law for the continuation or conversion of such coverage;

(II) the issuer of the policy substantially violated a material provision of the policy; or

(III) the issuer (or an agent or other entity acting on the issuer's behalf) materially misrepresented the policy's provisions in marketing the policy to the individual.

(v) The individual

(I) was enrolled under a medicare supplemental policy under this section,

(II) subsequently terminates such enrollment and enrolls, for the first time, with any Medicare+Choice organization under a Medicare+Choice plan under part C of this subchapter, any eligible organization under a contract under section 1395mm of this title, any similar organization operating under demonstration project authority, any PACE provider under section 1395see of this title, or any policy described in subsection (t) of this section, and

(III) the subsequent enrollment under subclause (II) is terminated by the enrollee during any period within the first 12 months of such enrollment (during which the enrollee is permitted to terminate such subsequent enrollment under section 1395w–21(e) of this title).

(vi) The individual, upon first becoming eligible for benefits under part A of this subchapter at age 65, enrolls in a Medicare+Choice plan under part C of this subchapter or in a PACE program under section 1395see of this title, and disenrolls from such plan or such program by not later than 12 months after the effective date of such enrollment.

(C)(i) Subject to clauses (ii) and (iii), a medicare supplemental policy described in this subparagraph is a medicare supplemental policy which has a benefit package classified as "A", "B", "C", or "D" under the standards established under subsection (p)(2) of this section.

(ii)(I) Subject to subclause (II), only for purposes of an individual described in subparagraph (B)(v), a medicare supplemental policy described in this subparagraph is the same medicare supplemental policy referred to in such subparagraph in which the individual was most recently previously enrolled, if available from the same issuer, or, if not so available, a policy described in clause (i).

(II) If the medicare supplemental policy referred to in subparagraph (B)(v) was a medigap Rx policy (as defined in subsection (v)(6)(A) of this section), a medicare supplemental policy described in this subparagraph is such policy in which the individual was most recently enrolled as modified under subsection (v)(2)(C)(i) of this section or, at the election of the individual, a policy referred to in subsection (v)(3)(A)(i) of this section.

(iii) Only for purposes of an individual described in subparagraph (B)(vi) and subject to subsection (v)(1) of this section, a medicare supplemental policy described in this subparagraph shall include any medicare supplemental policy.

(iv) For purposes of applying this paragraph in the case of a State that provides for offering of benefit packages other than under the classification referred to in clause (i), the references to benefit packages in such clause are deemed references to comparable benefit packages offered in such State.

(D) At the time of an event described in subparagraph (B) because of which an individual ceases enrollment or loses coverage or benefits under a contract or agreement, policy, or plan, the organization that offers the contract or agreement, the insurer offering the policy, or the administrator of the plan, respectively, shall notify the individual of the rights of the individual under this paragraph, and obligations of is-
ers of medicare supplemental policies, under subparagraph (A).

(E) For purposes of subparagraph (A), the time period specified in this subparagraph is—

(i) in the case of an individual described in subparagraph (B)(i), the period beginning on the date the individual receives a notice of termination or cessation of all supplemental health benefits (or, if no such notice is received, notice that a claim has been denied because of such a termination or cessation) and ending on the date that is 63 days after the applicable notice;

(ii) in the case of an individual described in clause (ii), (iii), (v), or (vi) of subparagraph (B) whose enrollment is terminated involuntarily, the period beginning on the date that the individual receives a notice of termination and ending on the date that is 63 days after the date the applicable coverage is terminated;

(iii) in the case of an individual described in subparagraph (B)(iv)(I), the period beginning on the earlier of (I) the date that the individual receives a notice of termination, a notice of the issuer’s bankruptcy or insolvency, or other such similar notice, if any, and (II) the date that the applicable coverage is terminated, and ending on the date that is 63 days after the date the coverage is terminated;

(iv) in the case of an individual described in clause (ii), (iii), (iv)(II), (iv)(III), (v), or (vi) of subparagraph (B) who disenrolls voluntarily, the period beginning on the date that is 60 days before the effective date of the disenrollment and ending on the date that is 63 days after such effective date; and

(v) in the case of an individual described in subparagraph (B) but not described in the preceding provisions of this subparagraph, the period beginning on the effective date of the disenrollment and ending on the date that is 63 days after such effective date.

(F)(i) Subject to clause (ii), for purposes of this paragraph—

(I) in the case of an individual described in subparagraph (B)(v) (or deemed to be so described, pursuant to this subparagraph) whose enrollment with an organization or provider described in subclause (II) of such subparagraph is involuntarily terminated within the first 12 months of such enrollment, and who, without an intervening enrollment, enrolls with another such organization or provider, such subsequent enrollment shall be deemed to be an initial enrollment described in such subparagraph; and

(II) in the case of an individual described in clause (vi) of subparagraph (B) (or deemed to be so described, pursuant to this subparagraph) whose enrollment with a plan or program described in such clause is involuntarily terminated within the first 12 months of such enrollment, and who, without an intervening enrollment, enrolls in another such plan or program, such subsequent enrollment shall be deemed to be an initial enrollment described in such clause.

(ii) For purposes of clauses (v) and (vi) of subparagraph (B), no enrollment of an individual with an organization or provider described in clause (v)(II), or with a plan or in a program described in clause (vi), may be deemed to be an initial enrollment under this clause after the 2-year period beginning on the date on which the individual first enrolled with such an organization, provider, plan, or program.

(4) Any issuer of a medicare supplemental policy that fails to meet the requirements of this subsection is subject to a civil money penalty of not to exceed $5,000 for each such failure. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(t) Medicare select policies

(1) If a medicare supplemental policy meets the 1991 NAIC Model Regulation or 1991 Federal Regulation and otherwise complies with the requirements of this section except that benefits under the policy are restricted to items and services furnished by certain entities (or reduced benefits are provided when items or services are furnished by other entities), the policy shall nevertheless be treated as meeting those standards if—

(A) full benefits are provided for items and services furnished through a network of entities which have entered into contracts or agreements with the issuer of the policy;

(B) full benefits are provided for items and services furnished by other entities if the services are medically necessary and immediately required because of an unforeseen illness, injury, or condition and it is not reasonable given the circumstances to obtain the services through the network;

(C) the network offers sufficient access;

(D) the issuer of the policy has arrangements for an ongoing quality assurance program for items and services furnished through the network;

(E)(i) the issuer of the policy provides to each enrollee at the time of enrollment an explanation of (I) the restrictions on payment under the policy for services furnished other than by or through the network, (II) out of area coverage under the policy, (III) the policy’s coverage of emergency services and urgently needed care, and (IV) the availability of a policy through the entity that meets the standards in the 1991 NAIC Model Regulation or 1991 Federal Regulation without reference to this subsection and the premium charged for such policy, and

(ii) each enrollee prior to enrollment acknowledges receipt of the explanation provided under clause (i); and

(F) the issuer of the policy makes available to individuals, in addition to the policy described in this subsection, any policy (otherwise offered by the issuer to individuals in the State) that meets the standards in the 1991 NAIC Model Regulation or 1991 Federal Regulation and other requirements of this section without reference to this subsection.

(2) If the Secretary determines that an issuer of a policy approved under paragraph (1)—
(A) fails substantially to provide medically necessary items and services to enrollees seeking such items and services through the issuer's network, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual,

(B) imposes premiums on enrollees in excess of the premiums approved by the State,

(C) acts to expel an enrollee for reasons other than nonpayment of premiums, or

(D) does not provide the explanation required under paragraph (1)(E)(i) or does not obtain the acknowledgment required under paragraph (1)(E)(ii),

the issuer is subject to a civil money penalty in an amount not to exceed $25,000 for each such violation. The provisions of section 1320a–7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(3) The Secretary may enter into a contract with an entity whose policy has been certified under paragraph (1) or has been approved by a State under subsection (b)(1)(H) of this section to determine whether items and services (furnished to individuals entitled to benefits under this subchapter and under that policy) are not allowable under section 1385u(a)(1) of this title. Payments to the entity shall be in such amounts that the Secretary finds appropriate. Paragraph (1), the first sentence of paragraph (2)(A), paragraph (2)(B), paragraph (3)(C), paragraph (3)(D), and paragraph (3)(E) of section 1395u(b) of this title shall apply to the entity.

(u) Additional rules relating to individuals enrolled in MSA plans and in private fee-for-service plans

(1) It is unlawful for a person to sell or issue a policy described in paragraph (2) to an individual with knowledge that the individual has in effect under section 1395w–21 of this title an election of an MSA plan or a Medicare+Choice private fee-for-service plan.

(2)(A) A policy described in this subparagraph is a health insurance policy (other than a policy described in subparagraph (B)) that provides for coverage of expenses that are otherwise required to be counted toward meeting the annual deductible amount provided under the MSA plan.

(B) A policy described in this subparagraph is any of the following:

(i) A policy that provides coverage (whether through insurance or otherwise) for accidents, disability, dental care, vision care, or long-term care.

(ii) A policy of insurance to which subparagraph (A)(ii) does not apply and that provides for coverage of expenses that are otherwise required to be counted toward meeting the annual deductible amount provided under the MSA plan.

(iii) A policy of insurance that provides coverage for a specified disease or illness.

(iv) A policy of insurance that pays a fixed amount per day (or other period) of hospitalization.

(v) Rules relating to medigap policies that provide prescription drug coverage

(1) Prohibition on sale, issuance, and renewal of new policies that provide prescription drug coverage

(A) In general

Notwithstanding any other provision of law, on or after January 1, 2006, a medigap Rx policy (as defined in paragraph (6)(A)) may not be sold, issued, or renewed under this section—

(i) to an individual who is a part D enrollee (as defined in paragraph (6)(B)); or

(ii) except as provided in subparagraph (B), to an individual who is not a part D enrollee.

(B) Continuation permitted for non-part D enrollees

Subparagraph (A)(ii) shall not apply to the renewal of a medigap Rx policy that was issued before January 1, 2006.

(C) Construction

Nothing in this subsection shall be construed as preventing the offering on and after January 1, 2006, of "H", "I", and "J" policies described in paragraph (2)(D)(i) if the benefit packages are modified in accordance with paragraph (2)(C).

(2) Elimination of duplicative coverage upon part D enrollment

(A) In general

In the case of an individual who is covered under a medigap Rx policy and enrolls under a part D plan—

(i) before the end of the initial part D enrollment period, the individual may—

(I) enroll in a medigap supplemental policy without prescription drug coverage under paragraph (3); or

(II) continue the policy in effect subject to the modification described in subparagraph (C)(i); or

(ii) after the end of such period, the individual may continue the policy in effect subject to such modification.

(B) Notice required to be provided to current policyholders with medigap Rx policy

No medigap supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) of this section unless the issuer provides written notice (in accordance with standards of the Secretary established in consultation with the National Association of Insurance Commissioners) during the 60-day period immediately preceding the initial part D enrollment period, to each individual who is a policyholder or certificate holder of a medigap Rx policy (at the most recent available address of that individual) of the following:

(i) If the individual enrolls in a plan under part D of this subchapter during the
initial enrollment period under section 1395w–101(b)(2)(A) of this title, the individual has the option of—

(I) continuing enrollment in the individual's current plan, but the plan's coverage of prescription drugs will be modified under subparagraph (C)(i); or

(II) enrolling in another medicare supplemental policy pursuant to paragraph (3).

(ii) If the individual does not enroll in a plan under part D of this subchapter during such period, the individual may continue enrollment in the individual's current plan without change, but—

(I) the individual will not be guaranteed the option of enrollment in another medicare supplemental policy pursuant to paragraph (3); and

(II) if the current plan does not provide creditable prescription drug coverage (as defined in section 1395w–113(b)(4) of this title), notice of such fact and that there are limitations on the periods in a year in which the individual may enroll under a part D plan and any such enrollment is subject to a late enrollment penalty.

(iii) Such other information as the Secretary may specify (in consultation with the National Association of Insurance Commissioners), including the potential impact of such election on premiums for medicare supplemental policies.

(C) Modification

(i) In general

The policy modification described in this subparagraph is the elimination of prescription coverage for expenses of prescription drugs incurred after the effective date of the individual's coverage under a part D plan and the appropriate adjustment of premiums to reflect such elimination of coverage.

(ii) Continuation of renewability and application of modification

No medicare supplemental policy of an issuer shall be deemed to meet the standards in subsection (c) of this section unless the issuer—

(I) continues renewability of medigap Rx policies that it has issued, subject to subclause (II); and

(II) applies the policy modification described in clause (i) in the cases described in clauses (i)(II) and (ii) of subparagraph (A).

(D) References to Rx policies

(i) H, I, and J policies

Any reference to a benefit package classified as "H", "I", or "J" (including the benefit package classified as "J" with a high deductible feature, as described in subsection (p)(11) of this section) under the standards established under subsection (p)(2) of this section shall be construed as including a reference to such a package as modified under subparagraph (C) and such packages as modified shall not be counted as a separate benefit package under such subsection.

(ii) Application in waivered States

Except for the modification provided under subparagraph (C), the waivers previously in effect under subsection (p)(2) of this section shall continue in effect.

(3) Availability of substitute policies with guaranteed issue

(A) In general

The issuer of a medicare supplemental policy—

(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as "A", "B", "C", or "F" (including the benefit package classified as "F" with a high deductible feature, as described in subsection (p)(11) of this section), under the standards established under subsection (p)(2) of this section, or a benefit package described in subparagraph (A) or (B) of subsection (w)(2) of this section and that is offered and is available for issuance to new enrollees by such issuer;

(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical condition; and

(iii) may not impose an exclusion of benefits based on a pre-existing condition under such policy, in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the effective date of the individual's coverage under a part D plan.

(B) Individual covered

An individual described in this subparagraph with respect to the issuer of a medicare supplemental policy is an individual who—

(i) enrolls in a part D plan during the initial part D enrollment period;

(ii) at the time of such enrollment was enrolled in a medigap Rx policy issued by such issuer; and

(iii) terminates enrollment in such policy and submits evidence of such termination along with the application for the policy under subparagraph (A).

(C) Special rule for waivered States

For purposes of applying this paragraph in the case of a State that provides for offering of benefit packages other than under the classification referred to in subparagraph (A)(i), the references to benefit packages in such subparagraph are deemed references to comparable benefit packages offered in such State.

(4) Enforcement

(A) Penalties for duplication

The penalties described in subsection (d)(3)(A)(ii) of this section shall apply with respect to a violation of paragraph (1)(A).

(B) Guaranteed issue

The provisions of paragraph (4) of subsection (s) of this section shall apply with
respect to the requirements of paragraph (3) in the same manner as they apply to the requirements of such subsection.

(5) Construction
Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met with respect to a part D enrollee through the continuation of the policy subject to modification under paragraph (2)(C) or the offering of a substitute policy under paragraph (3). The previous sentence shall not be construed to affect the guaranteed renewability of such a modified or substitute policy.

(6) Definitions
For purposes of this subsection:

(A) Medigap Rx policy
The term "medigap Rx policy" means a medicare supplemental policy—
(i) which has a benefit package classified as "H", "I", or "J" (including the benefit package classified as "J" with a high deductible feature, as described in subsection (p)(11) of this section) under the standards established under subsection (p)(2) of this section, without regard to this subsection; and
(ii) to which such standards do not apply (or to which such standards have been waived under subsection (p)(6) of this section) but which provides benefits for prescription drugs.

Such term does not include a policy with a benefit package as classified under clause (i) which has been modified under paragraph (2)(C)(i).

(B) Part D enrollee
The term "part D enrollee" means an individual who is enrolled in a part D plan.

(C) Part D plan
The term "part D plan" means a prescription drug plan or an MA–PD plan (as defined for purposes of part D of this subchapter).

(D) Initial part D enrollment period
The term "initial part D enrollment period" means the initial enrollment period described in section 1395w–101(b)(2)(A) of this title.

(w) Development of new standards for medicare supplemental policies

(1) In general
The Secretary shall request the National Association of Insurance Commissioners to review and revise the standards for benefit packages under subsection (p)(1) of this section, taking into account the changes in benefits resulting from enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and to otherwise update standards to reflect other changes in law included in such Act. Such revision shall incorporate the inclusion of the 2 benefit packages described in paragraph (2). Such revisions shall be made consistent with the rules applicable under subsection (p)(1)(E) of this section with the reference to the "1991 NAIC Model Regulation" deemed a reference to the NAIC Model Regulation as published in the Federal Register on December 4, 1998, and as subsequently updated by the National Association of Insurance Commissioners to reflect previous changes in law (and subsection (v) of this section) and the reference to "date of enactment of this subsection" deemed a reference to December 8, 2003. To the extent practicable, such revision shall provide for the implementation of revised standards for benefit packages as of January 1, 2006.

(2) New benefit packages
The benefit packages described in this paragraph are the following (notwithstanding any other provision of this section relating to a core benefit package):

(A) First new benefit package
A benefit package consisting of the following:

(i) Subject to clause (ii), coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B of this subchapter, except there shall be no coverage of the part B deductible and coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

(ii) Coverage for all hospital inpatient coinsurance and 365 extra lifetime days of coverage of inpatient hospital services (as in the current core benefit package).

(iii) A limitation on annual out-of-pocket expenditures under parts A and B of this subchapter to $4,000 in 2006 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

(B) Second new benefit package
A benefit package consisting of the benefit package described in subparagraph (A), except as follows:

(i) Substitute "75 percent" for "50 percent" in clause (i) of such subparagraph.

(ii) Substitute "$2,000" for "$4,000" in clause (iii) of such subparagraph.

(x) Limitations on genetic testing and information

(1) Genetic testing

(A) Limitation on requesting or requiring genetic testing
An issuer of a medicare supplemental policy shall not request or require an individual or a family member of such individual to undergo a genetic test.

(B) Rule of construction
Subparagraph (A) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(C) Rule of construction regarding payment

(i) In general
Nothing in subparagraph (A) shall be construed to preclude an issuer of a medicare supplemental policy from obtaining
and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of subchapter XI and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (s)(2)(E).

(ii) Limitation

For purposes of clause (i), an issuer of a medicare supplemental policy may request only the minimum amount of information necessary to accomplish the intended purpose.

(D) Research exception

Notwithstanding subparagraph (A), an issuer of a medicare supplemental policy may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

(i) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that—

(I) compliance with the request is voluntary; and

(II) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(iii) No genetic information collected or acquired under this subparagraph shall be used for underwriting, determination of eligibility to enroll or maintain enrollment status, premium rating, or the creation, renewal, or replacement of a plan, contract, or coverage for health insurance or health benefits.

(iv) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this subparagraph, including a description of the activities conducted.

(v) The issuer complies with other conditions as the Secretary may by regulation require for activities conducted under this subparagraph.

(2) Prohibition on collection of genetic information

(A) In general

An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information for underwriting purposes (as defined in paragraph (3)).

(B) Prohibition on collection of genetic information prior to enrollment

An issuer of a medicare supplemental policy shall not request, require, or purchase genetic information with respect to any individual prior to such individual’s enrollment under the policy in connection with such enrollment.

(C) Incidental collection

If an issuer of a medicare supplemental policy obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of subparagraph (B) if such request, requirement, or purchase is not in violation of subparagraph (A).

(3) Definitions

In this subsection:

(A) Family member

The term “family member” means with respect to an individual, any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual.

(B) Genetic information

(i) In general

The term “genetic information” means, with respect to any individual, information about—

(I) such individual’s genetic tests,

(II) the genetic tests of family members of such individual, and

(III) subject to clause (iv), the manifestation of a disease or disorder in family members of such individual.

(ii) Inclusion of genetic services and participation in genetic research

Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

(iii) Exclusions

The term “genetic information” shall not include information about the sex or age of any individual.

(C) Genetic test

(i) In general

The term “genetic test” means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(ii) Exceptions

The term “genetic test” does not mean—

(I) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(II) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(D) Genetic services

The term “genetic services” means—
(i) a genetic test;  
(ii) genetic counseling (including obtaining, interpreting, or assessing genetic information); or
(iii) genetic education.

(E) Underwriting purposes

The term “underwriting purposes” means, with respect to a medicare supplemental policy—

(i) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the policy;  
(ii) the computation of premium or contribution amounts under the policy;  
(iii) the application of any pre-existing condition exclusion under the policy; and
(iv) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(F) Issuer of a medicare supplemental policy

The term “issuer of a medicare supplemental policy” includes a third-party administrator or other person acting for or on behalf of such issuer.

(4) Genetic information of a fetus or embryo

Any reference in this section to genetic information concerning an individual or family member of an individual shall—

(A) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and
(B) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

(y) Development of new standards for certain medicare supplemental policies

(1) In general

The Secretary shall request the National Association of Insurance Commissioners to review and revise the standards for benefit packages described in paragraph (2) under subsection (p)(1), to otherwise update standards to include requirements for nominal cost sharing to encourage the use of appropriate physicians’ services under part B. Such revisions shall be based on evidence published in peer-reviewed journals or current examples used by integrated delivery systems and made consistent with the rules applicable under subsection (p)(1)(E) with the reference to the “1991 NAIC Model Regulation” deemed a reference to the NAIC Model Regulation as published in the Federal Register on December 4, 1998, and as subsequently updated by the National Association of Insurance Commissioners to reflect previous changes in law and the reference to “date of enactment of this subsection” deemed a reference to March 23, 2010. To the extent practicable, such revision shall provide for the implementation of revised standards for benefit packages as of January 1, 2015.

(2) Benefit packages described

The benefit packages described in this paragraph are benefit packages classified as “C” and “F”.

Stat. 1979. For complete classification of this Act to the Code, see Short Title of 1989 Amendment note set out under section 1365 of this title and Tables.


Section 2701 of the Public Health Service Act, referred to in subsec. (s)(2)(D), is section 2701 of act July 1, 1944, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10108(a), title X, §10108(a), Mar. 23, 2010, 124 Stat. 154, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1202(a), title X, §10108(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

Part C of this subchapter, referred to in subsec. (s)(3)(B)(i), (v)(II), (vi), is classified to section 1395w–21 et seq. of this title.


Part C of subchapter XI, referred to in subsec. (x)(1)(C)(i), is classified to section 1320d et seq. of this title.


AMENDMENTS

2010—Subsec. (o)(1). Pub. L. 111–148, §3210(b), substituted ``(w), and (y)'' for ``(w), and (w)''.


Subsec. (s)(2)(E)(ii). Pub. L. 110–233, §104(a), added subpars. (E) and (F).


2007—Subsec. (o)(5). Pub. L. 110–161 substituted ``The Secretary may'' for ``(A) The Comptroller General shall periodically, not less often than once every 3 years, and strike out ``and to the Secretary'' after ``State involved and subpar. (B) which read as follows: ``The Secretary may independently perform such compliance audits.''.


Subsec. (d)(3)(B)(iii)(II). Pub. L. 108–173, §736(e)(2), substituted to the best of the issuer’s or seller’s knowledge'' for to the best of the issuer’s or seller’s knowledge'.

Subsec. (g)(1). Pub. L. 108–173, §104(b)(2)(A), inserted a prescription drug plan under part D of this subchapter after but does not include''.


2000—Subsec. (s)(3)(A). Pub. L. 106–554, §736(e)(6) [title VI, §618(a)(1)], in concluding provisions, substituted seeks to enroll under the policy during the period specified in subparagraph (E) for subject to subparagraph (E), seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such subparagraph''.

Subsec. (s)(3)(E). Pub. L. 106–554, §736(e)(6) [title VI, §618(a)(2)], added subpar. (E) and struck out former subpar. (E) which read as follows: (E) An individual described in subparagraph (B)(ii) may elect to apply subparagraph (A) by substituting, for the date of termination of enrollment, the date on which the individual was notified by the Medicare+Choice organization of the impending termination of the Medicare+Choice plan it offers in the area in which the individual resides, but only if the individual disenrolls from the plan as a result of such notification.

(ii) In the case of an individual making such an election, the issuer involved shall accept the application of the individual submitted before the date of termination of enrollment, but the coverage under subparagraph (A) shall only become effective upon termination of coverage under the Medicare+Choice plan involved.


1999—Subsec. (g)(1). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(13)], struck out or after but does not include'’.

Subsec. (q)(5)(C). Pub. L. 106–170, §205(a)(1), inserted or paragraph (6) after this paragraph''.


Subsec. (s)(3)(A). Pub. L. 106–113, §1000(a)(6) [title VI, §536(a)(1)], inserted before period at end or the individual is 65 years of age or older and is enrolled with a PACE provider under section 1395eee of this title, and there are circumstances that would permit the discontinuance of the individual’s enrollment with such provider under circumstances that are similar to the circumstances that would permit discontinuance of the individual’s election under the first sentence of such section if such individual were enrolled in a Medicare+Choice plan''.

Subsec. (s)(3)(B)(v). Pub. L. 106–113, §1000(a)(6) [title VI, §536(a)(3)], inserted any PACE provider under section 1395eee of this title or” after demonstration project authority’’.

Subsec. (s)(3)(B)(vi). Pub. L. 106–113, §1000(a)(6) [title VI, §536(a)(4)], inserted or in a PACE program under section 1395eee of this title after part C of this chapter and substituted such plan or such program'' for such plan''.


1998—Subsec. (j)(6). Pub. L. 105–362 struck out par. (6) which read as follows: ‘‘The Secretary shall report to
the Congress in March 1989 and in July 1990 on actions States have taken in adopting standards equal to or more stringent than the NAIC Model Transition Regu-
lar and the amended NAIC Model Regulation (or Fed-
eral model standards)."

1997—Subsec. (d)(3)(A)(i). Pub. L. 105–33, § 4003(a)(1)(A), inserted "(including an individual electing a Medicare+Choice plan under section 1395w–21 of this sec-
tion ‘‘after ‘‘(II)’’ and inserted ‘‘or in the case of an individual electing a Medicare+Choice plan, a medicare supplemental policy with knowledge that the policy duplicates health benefits to which the individual is otherwise entitled under the Medicare+Choice plan or under another medicare supplemental policy’’ before comma at end.

Pub. L. 105–33, § 4031(c), inserted "a policy described in clause (v),’’ after ‘‘Medi-
care supplemental policy’’.

Subsec. (g)(1). Pub. L. 105–33, § 4003(a)(2), inserted "includ-
ing any Medicare+Choice plan’’ after ‘‘health insurance policies’’.

(11).

Subsec. (a)(2)(B). Pub. L. 105–33, § 4031(b)(1), sub-
stituted ‘‘subparagraphs (C) and (D)’’ for ‘‘subparagraph (C)’’.

Subsec. (a)(2)(D). Pub. L. 105–33, § 4031(b)(2), added sub-
par. (D).

(3). Former par. (3) redesignated (4).

Pub. L. 105–33, § 4031(a)(10), redesignated ‘‘requirements of this subsec-
tion’’ for ‘‘requirements of paragraphs (1) and (2)’’ and redesignated par. (3) as (4).


stituted ‘‘clause (i)’’ for ‘‘clause (ii)’’.


Subsec. (d)(3)(C). Pub. L. 104–191, § 271(b)(1), sub-
stituted ‘‘with respect to’’ for ‘‘with respect to’’ (i) and struck out before period at end ‘‘(i) the sale or issu-
ance of a policy or plan described in subparagraph (A)(i)(I) (other than a medicare supplemental policy to an individual entitled to any medical assistance under subchapter XIX of this chapter) under which all the benefits are fully payable directly to or on behalf of the individual without regard to other health benefit coverage of the individual but only if (for policies sold or issued more than 60 days after the date the statements are published or promulgated under subparagraph (D)) there is disclosed in a prominent manner as part of (or together with) the application the applicable statement (specified under subparagraph (D)) of the extent to which benefits payable under the policy or plan dupli-
cate benefits under this subchapter, or (ii) the sale or issuance of a policy or plan described in subparagraph (A)(i)(I) under which all the benefits are fully payable directly to or on behalf of the individual without regard to other health benefit coverage of the individual’’.

Subsec. (d)(3)(D). Pub. L. 104–191, § 271(b)(2), struck out subpar. (D) which provided for development of statements for various types of health insurance poli-
cies sold or issued to persons entitled to health benefits under this subchapter regarding extent to which bene-
fits payable under those policies duplicate benefits under this subchapter 1994—Subsec. (a)(2). Pub. L. 103–432, § 171(c)(1)(B), in closing provisions substituted ‘‘on and after the effective
date specified in subsection (p)(1)(C) of this sec-
tion’’ for ‘‘after the effective date of the NAIC or Fed-
eral model standards with respect to the policy’’.

Subsec. (a)(2)(A). Pub. L. 103–432, § 171(c)(1)(A), sub-
stituted ‘‘1991 NAIC Model Regulation or 1991 Federal model Regulation’’ for ‘‘NAIC standards or the Federal model standards’’.

Subsec. (b)(1). Pub. L. 103–432, § 171(e)(2), substituted ‘‘paragraph (F)’’ for ‘‘subsection (F)’’ in last sentence.

Pub. L. 103–432, § 171(c)(4), substituted the ‘‘Secretary determines’’ for ‘‘the Secretary determines’’ in intro-
ductive provisions.

Pub. L. 103–432, § 171(c)(2), in last sentence substituted ‘‘Each report’’ for ‘‘The report’’, ‘‘fail to meet the standards and requirements’’ for ‘‘fail to meet the standards’’, ‘‘compliance, information regarding’’ for ‘‘compliance, and information regarding’’, and ‘‘Commissioners may specify’’ for ‘‘Commissioners, may specify’’.


Subsec. (d)(3)(A). Pub. L. 103–432, § 171(d)(1)(D), struck out at end ‘‘This subsection shall not apply to such a seller until such date as the Secretary publishes a list of the standardized benefit packages that may be of-
fered consistent with subsection (p) of this section.’’

Pub. L. 103–432, § 171(b)(3)(C), designated third sentence as cl. (ii), substituted ‘‘clause (i) with respect to the sale of a medicare supplemental policy’’ for ‘‘the previous sentence’’, and struck out ‘‘and the statement under such subparagraph indicates on its face that the sale of the policy will not duplicate health benefits to which the individual is otherwise entitled’’ after ‘‘compliance with subparagraph (B)’’.

Pub. L. 103–432, § 171(d)(1)(B), designated second sentence as cl. (ii) and substituted ‘‘Whoever violates clause (i)’’ for ‘‘Whoever violates the previous sentence’’.

Pub. L. 103–432, § 171(d)(1)(A), designated first sentence as cl. (i) and amended it generally. Prior to amendment, first sentence read as follows: ‘‘It is un-
lawful for a person to sell or issue a health insurance policy to an individual entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, with knowledge that such policy duplicates health benefits to which such individual is otherwise entitled, other than benefits to which he is entitled under a requirement of State or Federal law (other than this subchapter or subchapter XIX of this chapter).’’

Subsec. (d)(3)(B)(i)(I). Pub. L. 103–432, § 171(d)(2)(A), struck out ‘‘65 years of age or older’’ before ‘‘may be el-
ige’’.

Subsec. (d)(3)(B)(i)(I). Pub. L. 103–432, § 171(d)(2)(B), (C), substituted ‘‘has a medicare supplemental policy’’ for ‘‘has another medicare supplemental policy’’ and ‘‘sale of a medicare supplemental policy’’ for ‘‘sale of such a policy’’.


Subsec. (d)(3)(B)(ii)(III). Pub. L. 103–432, § 171(d)(2)(E), amended subcl. (III) generally. Prior to amendment, subcl. (III) read as follows: ‘‘Subclause (I) also shall not apply if a State Medicaid plan under subchapter XIX of this chapter pays the premiums for the policy, or pays less than an individual’s (who is described in section 1396d(p)(1) of this title) full liability for medicare cost sharing as defined in section 1396d(p)(3)(A) of this title’’.

Subsec. (d)(3)(C). Pub. L. 103–432, § 171(d)(3)(A), substituted ‘‘(i) the sale or issuance of a group policy’’ for
"the selling of a group policy" and added cls. (ii) and (iii).


Subsec. (d)(4)(D). Pub. L. 103–432, § 171(k)(1), struck out before period at end "...if such policy expires not more than 12 months after the date on which the duplicate copy is mailed".


Subsec. (g)(1). Pub. L. 103–432, § 171(f)(1), substituted "an eligible organization (as defined in section 1395mm(b) of this title) if the policy or plan provides benefits pursuant to a contract under section 1395mm of this title or an approved demonstration project described in section 683(c) of the Social Security Amendments of 1983, section 2355 of the Deficit Reduction Act of 1984, or section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, or, during the period beginning on the date specified in subsection (p)(1)(C) of this section and ending on December 31, 1985, a policy or plan of an organization if the policy or plan provides benefits pursuant to an agreement under section 1395mm(a)(1)(A) of this title for "a health maintenance organization or other direct service organization which offers benefits under this subchapter, including such services under a contract under section 1395mm of this title or an agreement under section 1395mm of this title."


Subsec. (p)(1)(A). Pub. L. 103–432, § 171(a)(2)(A), in introductory provisions, substituted "changes the revised NAIC Model Regulation as changed under this subparagraph (such changed regulation referred to in this section as the ‘1991 NAIC Model Regulation’) for ‘‘included a reference to the NAIC standards’’ for "‘promulgates’, and in closing provisions, struck out "(such limitations, language, definitions, format, and standards referred to collectively in this subsection as ‘NAIC standards’,)" before "subsection (g)(2)(A) of this section" and substituted "were a reference to the revised NAIC Model Regulation as changed under this subparagraph (such changed regulation referred to in this section as the ‘1991 NAIC Model Regulation’) for ‘‘included a reference to the NAIC standards’’ for "one subparagraph (such changed regulation referred to in this section as the ‘1991 NAIC Model Regulation’) for ‘‘consistent with paragraph (1)(A)’’ for ‘‘consistent with this subchapter’’.

Subsec. (p)(1)(B). Pub. L. 103–432, § 171(a)(2)(B), substituted "the make the changes in the revised NAIC Model Regulation for ‘‘promulgate NAIC standards’, ‘‘a regulation for ‘‘limitations, language, definitions, format, and standards described in clauses (i) through (iv) of such subparagraph (in this subsection referred to collectively as ‘Federal standards’)’, and were a reference to the revised NAIC Model Regulation as changed by the Secretary under this subparagraph (such changed regulation referred to in this section as the ‘1991 Federal Regulation’)’ for ‘‘included a reference to the Federal standards’’ for "the make the changes in the revised NAIC Model Regulation for ‘‘promulgate NAIC standards’, ‘‘a regulation for ‘‘limitations, language, definitions, format, and standards described in clauses (i) through (iv) of such subparagraph (in this subsection referred to collectively as ‘Federal standards’)’, and were a reference to the revised NAIC Model Regulation as changed by the Secretary under this subparagraph (such changed regulation referred to in this section as the ‘1991 Federal Regulation’)’ for ‘‘included a reference to the Federal standards’’ for "the make the changes in the revised NAIC Model Regulation for subsection (p)(1)(C), and, inserted "after the effective date of these provisions’’ after "the 90 percent level''.


Subsec. (p)(4)(A). Pub. L. 103–432, § 171(a)(2)(F), inserted "or paragraph (6)’’ after "paragraph (B)’’.

Subsec. (p)(6). Pub. L. 103–432, § 171(a)(2)(H), substituted "described in clauses (i) through (iii) of paragraph (1)(A)’’ for ‘‘in regard to the limitation of benefits described in paragraph (4)’’.


Subsec. (p)(8). Pub. L. 103–432, § 171(a)(2)(J), substituted "on and after the effective date specified in paragraph (1)(C)’’ for '‘paragraph (1)’’.


Subsec. (p)(10). Pub. L. 103–432, § 171(a)(2)(N), substituted "consistent with paragraph (1)(A)’’ for ‘‘consistent with this subchapter’’.

Subsec. (q)(2). Pub. L. 103–432, § 171(b)(1), substituted "paragraph (4)’’ for "paragraph (2)’’.

Subsec. (q)(4). Pub. L. 103–432, § 171(b)(2), substituted "issuer of the replacement policy’’ for "the succeeding issuer’’.

Subsec. (q)(5)(A), (B). Pub. L. 103–432, § 171(d)(4), made technical amendment to the reference to a subchapter XIX of this chapter to correct reference to corresponding provision of original act.

Subsec. (r)(1). Pub. L. 103–432, § 171(e)(1)(A), (E), in introductory provisions substituted "or, if otherwise provide coverage after the date described in subsection (p)(1)(C) of this section’’ for "or sold’’ and inserted at end of closing provisions ‘‘For the purpose of calculating the refund or credit required by paragraph (1)(B) for a policy issued before the date specified in subsection (p)(1)(C) of this section, the refund or credit calculation shall be based on the aggregate benefits provided and premiums collected under all such policies issued by an insurer in a State (separated as to individual and group policies) and shall be based only on aggregate benefits provided and premiums collected under such policies after the date specified in section 171(m)(4) of the Social Security Act Amendments of 1994’’.


Pub. L. 103–432, § 171(e)(1)(B), inserted "or periods after the effective date of these provisions’’ after "the policy can be expected’’.

Subsec. (r)(1)(B). Pub. L. 103–432, § 171(e)(1)(D), inserted before period at end ‘‘, treating policies of the same type as a single policy for each standard package’’.


Subsec. (r)(6)(A). Pub. L. 103–432, § 171(e)(1)(L), substituted ‘‘fails to provide refunds or credits as required
in paragraph (1)(B)“ for “issues a policy in violation of the loss ratio requirements of this subsection” and “policy issued for which such failure occurred” for “such violation.”

Subsec. (d)(6)(B). Pub. L. 103–432, §171(e)(1)(M), substituted “to the policyholder or, in the case of a group policy, to the certificate holder” for “to policyholders.”

Subsec. (e)(2)(A). Pub. L. 103–432, §171(g)(1), (2), substituted “in the case of an individual for whom an application is submitted prior to or for “for which an application is submitted” and “as of the first day on which the individual is 65 years of age or older and is enrolled for benefits under part B” for “in which the individual (who is 65 years of age or older) first is enrolled for benefits under part B.”

Subsec. (e)(2)(B). Pub. L. 103–432, §171(g)(3), substituted “before the policy became effective” for “before it became effective.”

Subsec. (h)(1). Pub. L. 103–432, §171(h)(1)(A), (B), substituted “‘If a medical supplemental policy meets the 1991 NAIC Model Regulation or 1991 Federal Regulation for ‘If a policy meets the NAIC Model Standards’.”


Subsec. (t)(2). Pub. L. 103–432, §171(h)(1)(E), inserted “the violation” before “is subject to a civil money penalty” in concluding provisions.


Subsec. (a). Pub. L. 101–508, §4353(a)(2), designated existing provisions as par. (1) and added par. (2).


Subsec. (b)(1). Pub. L. 101–508, §4353(c)(5), inserted at end “The report required under subsection (F) shall include information on loss ratios of policies sold in the State, frequency and types of instances in which policies approved by the State fail to meet the standards of this paragraph, actions taken by the State to bring such policies into compliance, and information regarding State programs implementing consumer protection provisions, and such further information as the Secretary in consultation with the National Association of Insurance Commissioners, may specify.”

Pub. L. 101–508, §4353(b)(1), (2), substituted “the Secretary” for “Supplemental Health Insurance Panel (established under paragraph (2))” in introductory provisions for “the Panel” in concluding provisions.

Pub. L. 101–508, §4207(k)(1), formerly §4207(k)(1), as renumbered by Pub. L. 103–432, §160(c)(4), which directed the amendment of third sentence of par. (1) by striking out “(k)(4),” was executed by making the deletion after “subsections (k)(3),” in concluding provisions to reflect the probable intent of Congress.

Subsec. (b)(1)(G). Pub. L. 101–508, §4355(c), which directed amendment of par. (1) by adding at the end thereof a new subpar. (G), was executed by adding the new subpar. (G) immediately following subpar. (F) to reflect the probable intent of Congress.


Subsec. (b)(2). Pub. L. 101–508, §4353(b)(4), amended par. (2) generally. Prior to amendment, par. (2) read as follows:

“(A) There is hereby established a panel (hereinafter in this section referred to as the ‘Panel’) to be known as the Supplemental Health Insurance Panel. The Panel shall consist of the Secretary, who shall serve as the Chairman, and four State commissioners or superintendent of insurance, who shall be appointed by the Secretary and serve at his pleasure. Such members shall first be appointed not later than December 31, 1980.

“(B) A majority of the members of the Panel shall constitute a quorum, but a lesser number may conduct hearings.

“(C) The Secretary shall provide such technical, secretarial, clerical, and other assistance as the Panel may require.

“(D) There are authorized to be appropriated such sums as may be necessary to carry out this paragraph.

“(E) Members of the Panel shall be allowed, while away from their homes or regular places of business in the performance of services for the Panel, travel expenses (including per diem in lieu of subsistence) in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5.”

Subsec. (c). Pub. L. 101–508, §4357(a)(1), inserted “or the requirement described in subsection (s) of this section” after “paragraph (3)” in introductory provisions.

Pub. L. 101–508, §4355(a)(2), struck out at end “For purposes of paragraph (2), policies issued as a result of solicitations of individuals through the mails or by mass media advertising (including both print and broadcast advertising) shall be deemed to be individual policies.”

Subsec. (c)(1). Pub. L. 101–508, §4358(b)(1), inserted before semicolon at end “except as otherwise provided by subsection (t) of this section”.

Subsec. (c)(2). Pub. L. 101–508, §4353(a)(1), amended par. (2) generally. Prior to amendment, par. (2) read as follows: “can be expected (as estimated for the entire period for which rates are computed to provide coverage, on the basis of incurred claims experience and earned premiums for such period and in accordance with accepted actuarial principles and practices) to result in payment of benefits in the aggregate amount of premiums collected in the case of group policies and at least 90 percent of the aggregate amount of premiums collected in the case of individual policies”.


Subsec. (d)(3)(A). Pub. L. 101–508, §4354(a)(1), substituted “It is unlawful for a person to sell or issue” for “Whoever knowingly sells,” “duplicates health benefits” for “substantially duplicates health benefits,” “Whoever violates the previous sentence shall be fined” for “shall be fined”, “(other than this subchapter or subchapter XIX of this chapter)” for “(other than this subchapter)”, and “$25,000 (or $15,000”, in the case of a person other than the issuer of the policy)” for “$5,000” and inserted at end “A seller (who is not the issuer of a health insurance policy) shall not be considered to violate the previous sentence if the policy is sold in compliance with subparagraph (B) and the statement under such subparagraph indicates on its face that the sale of the policy will not duplicate any health benefits to which the individual is otherwise entitled. This subsection shall not apply to such a seller until such date as the Secretary publishes a list of the
standardized benefit packages that may be offered consistent with subsection (p) of this section.”

Subsec. (d)(3)(B). Pub. L. 101–508, § 4354(a)(2), amended subsec. (B) generally. Prior to amendment, subpar. (B) read as follows: “For purposes of this paragraph, benefits which are payable to or on behalf of an individual without regard to other health benefit coverage of such individual, shall not be considered as duplicative.”

Subsec. (d)(4)(B). Pub. L. 101–508, § 4353(d)(1), struck out at end “For purposes of this paragraph, a medicare supplemental policy shall be deemed to be approved by the commissioner or superintendent of insurance of a State if—”

“(i) the policy has been certified by the Secretary pursuant to subsection (c) of this section or was issued in a State with an approved regulatory program (as defined in subsection (g)(2)(B) of this section);”

“(ii) the policy has been approved by the commissioners or superintendents of insurance in States in which more than 30 percent of such policies are sold; or”

“(iii) the State has in effect a law which the commissioner or superintendent of insurance of the State has determined gives him the authority to review, and to approve, or effectively bar from sale in the State, such policy; except that such a policy shall not be deemed to be approved by a State commissioner or superintendent of insurance if the State notifies the Secretary that such policy has been submitted for approval to the State and has been specifically disapproved by such State after providing appropriate notice and opportunity for hearing pursuant to the procedures (if any) of the State.”

Subsec. (g)(1). Pub. L. 101–508, § 4356(a), inserted before period at end of first sentence “and does not include a policy or plan of a health maintenance organization or other direct service organization which offers benefits under this subchapter, including such services under a contract under section 1395m of this title or an agreement under section 1395f of this title.”


1989—Subsecs. (a), (b)(1), Pub. L. 101–234, § 303(a)(1)(A), substituted “subsections (k)(3), (c)(4), (m), and (n) of this section” for “subsection (k)(3) of this section”.

Subsec. (k)(1)(A). Pub. L. 101–234, § 303(a)(1)(B), inserted “except as provided in subsection (m) of this section,” before “subsection (g)(2)(A)”.

Subsec. (k)(3). Pub. L. 101–234, § 303(a)(1)(B)(ii), substituted “subject to subsections (l), (m), and (n) of this section” for “subsection (l) of this section”.

Subsecs. (m), (n). Pub. L. 101–234, § 203(a)(1)(C), added subsecs. (m) and (n).

1985—Subsec. (a). Pub. L. 100–360, § 4221(d)(1), substituted “subject to subsection (k)(3) of this section, such for “Such”.

Subsec. (b)(1). Pub. L. 100–360, § 4221(d)(2), substituted “subject to subsection (k)(3) of this section, for so long as” for “for so long as” in concluding provisions.

Subsec. (b)(1)(B). Pub. L. 100–360, § 4221(a)(1), substituted “through (4)” for “and (3)”.


Pub. L. 100–360, § 4221(b)(1), substituted “(A), (B), and (C)” for “(A) and (B)”.

Subsec. (b)(1)(D). Pub. L. 100–360, § 4221(b)(2), redesignated former subpars. (C) and (D) as (D) and (E), respectively.

Subsec. (b)(2)(A). Pub. L. 100–360, § 4221(f), substituted “appointed by the Secretary for ‘appointed by the President’.”

Subsec. (b)(3). Pub. L. 100–360, § 4221(e), added par. (3).
years beginning on or after the date that is 1 year after the date of enactment of this Act [May 21, 2008]."

**Effective Date of 1999 Amendments**

Pub. L. 106–170, title II, §205(b), Dec. 17, 1999, 113 Stat. 1900, provided that: "The amendments made by subsection (a) [amending this section] apply with respect to requests made after the date of the enactment of this Act [Dec. 17, 1999]."

Amendment by section 1000(a)(6) [title III, §321(k)(13), (14)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106–113, set out as a note under section 1395w–21 of this title.

Amendment by section 1000(a)(6) [title V, §501(a)(2)] of Pub. L. 106–113 applicable to notices of impending terminations or discontinuances made on or after Nov. 29, 1999, see section 1000(a)(6) [title V, §501(d)(1)] of Pub. L. 106–113, set out as a note under section 1395w–21 of this title.

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §536(b)], Nov. 29, 1999, 113 Stat. 1356, 1351A–391, provided that: "The amendments made by this section [amending this section] shall apply to terminals or discontinuances made on or after the date of the enactment of this Act [Nov. 29, 1999]."

**Effective Date of 1997 Amendment**

Section 4002(j)(2) of Pub. L. 105–33 provided that the amendment made by that section is effective Jan. 1, 1998.

Section 4032(b) of Pub. L. 105–33 provided that: "(1) GUARANTEED ISSUE.—The amendment made by subsection (a) [amending this section] shall take effect on July 1, 1998.

(2) LIMIT ON PREEXISTING CONDITION EXCLUSIONS.—The amendment made by subsection (b) [amending this section] shall apply to policies issued on or after July 1, 1998.

(3) CONFORMING AMENDMENT.—The amendment made by subsection (c) [amending this section] shall be effective as if included in the enactment of the Health Insurance Portability and Accountability Act of 1996 [Pub. L. 104–191]."

Section 4032(b) of Pub. L. 105–33 provided that: "(1) IN GENERAL.—The amendments made by subsection (a) [amending this section] shall take effect the date of the enactment of this Act [Aug. 5, 1997].

(2) TRANSITION.—The provisions of section 4031(e) [set out as a note below] shall apply with respect to this section in the same manner as they apply to section 4031 [amending this section and enacting provisions set out as notes below]."

**Effective Date of 1996 Amendment**

Section 271(d) of Pub. L. 104–191 provided that: "(1) Except as provided in this subsection, the amendment made by subsection (a) [amending this section] shall be effective as if included in the enactment of section 4354 of the Omnibus Budget Reconciliation Act of 1990 [Pub. L. 101–508].

(2)(A) Clause (vi) of section 1882(d)(3)(A) of the Social Security Act [subsection (d)(3)(A)(vi) of this section], as added by subsection (a), shall only apply to individuals applying for—

(i) a health insurance policy described in section 1882(d)(3)(A)(iv) of such Act (as added by subsection (a)), after the date of the enactment of this Act [Aug. 21, 1996], or

(ii) another health insurance policy after the end of the 30-day period beginning on the date of the enactment of this Act.

(B) A seller or issuer of a health insurance policy may substitute, for the disclosure statement described in clause (vii) of such section, the statement specified under subsection 1882(d)(3)(D) of the Social Security Act (as in effect before the date of the enactment of this Act), without the revision specified in such clause."

**Effective Date of 1994 Amendment**

Section 171(l) of Pub. L. 103–432 provided that: "The amendments made by this section [amending this section and sections 1320c–3, 1396b–2, and 1396b–4 of this title, repealing section 1395zz of this title, and enacting and amending provisions set out as notes below] shall be effective as if included in the enactment of OBRA–1990 [Pub. L. 101–508]; except that—

(1) the amendments made by subsection (d)(1) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 31, 1994], but no penalty shall be imposed under section 1882(d)(3)(A) of the Social Security Act [subsection (d)(3)(A) of this section] for an action occurring after the effective date of the amendments made by section 4354 of OBRA–1990 [see section 4354(c) of Pub. L. 101–508, set out as an Effective Date of 1990 Amendment note below] and before the date of the enactment of this Act with respect to the sale or issuance of a policy which is not unlawful under section 1882(d)(3)(A) of the Social Security Act [subsection (d)(3)(A)(ii) of this section] as amended by this section;

(2) the amendments made by subsection (d)(2)(A) [amending this section] and by subparagraphs (A), (B), and (E) of subsection (e)(1) [amending this section] shall be effective on the date specified in subsection (m)(4) [set out as a note below]; and

(3) the amendment made by subsection (g)(2) [amending this section] shall take effect on January 1, 1995, and shall apply to individuals who attain 65 years of age or older on or after the applicable effective date and before January 1, 1995, who were not covered under such section before January 1, 1995, the 6-month period specified in that section shall begin January 1, 1995.

**Effective Date of 1990 Amendment**

Section 4353(d)(2) of Pub. L. 101–508 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to policies mailed, or caused to be mailed, on and after July 1, 1991.

Section 4353(c) of Pub. L. 101–508 provided that: "The amendments made by this section [amending this section] shall apply to policies issued or sold more than 1 year after the date of the enactment of this Act [Nov. 5, 1990]."

Section 4355(d) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §171(l)(2), Oct. 31, 1994, 108 Stat. 4449, provided that: "The amendments made by this section [amending this section] shall apply to policies issued and renewed (or otherwise providing coverage after the date described in section 1882(p)(1)(C) of the Social Security Act [subsection (p)(1)(C) of this section]) or on or after the date specified in section 1882(p)(1)(C) of the Social Security Act."

Section 4356(b) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §171(l)(2), Oct. 31, 1994, 108 Stat. 4449, provided that: "The amendment made by subsection (a) [amending this section] shall take effect on the date specified in section 1882(p)(1)(C) of the Social Security Act [subsection (p)(1)(C) of this section]."

Section 4357(b) of Pub. L. 101–508 provided that: "The amendments made by subsection (a) [amending this section] shall take effect 1 year after the date of the enactment of this Act [Nov. 5, 1990]."

Amendment by section 4358(a), (b)(1), (2) of Pub. L. 101–508 only applicable in 15 States (as determined by Secretary of Health and Human Services) and such other States as elect such amendment to apply to them, and during the 6½-year period beginning with 1992, with such amendment to remain in effect beyond the 6½-year period unless the Secretary makes certain determinations, see section 4358(c) of Pub. L. 101–508, as amended, set out as a note under section 1320c–3 of this title.
Section 203(e) of Pub. L. 101–234 provided that: "The provisions of this section [amending this section, enacting provisions set out as notes under sections 1395b–2 and 1395mm of this title, and amending provisions set out as a note under this section] shall take effect January 1, 1990, except that the amendment made by subsection (d) [amending provisions set out as an Effective Date of 1988 Amendment note under this section] shall be effective as if included in the enactment of MCCA [Pub. L. 100–360]."

Effective Date of 1988 Amendment


"(1) Except as provided in paragraphs (2) and (3), the amendments made by this section [amending this section] shall take effect on the date of the enactment of this Act [July 1, 1988]."

"(2) The amendments made by subsections (a) and (b) [amending this section] shall become effective on the date specified in subsection (k)(1)(B) or (k)(2)(B) of section 1882 of the Social Security Act [amending this section, as added by subsection (d) of this section]."

"(3) The amendment made by subsection (e) [amending this section] shall apply to medicare supplemental policies as of January 1, 1989, with respect to advertising used on or after such date.

"(4) The Secretary of Health and Human Services shall provide for the reappointment of members to the Supplemental Health Insurance Panel (under section 1882(b)(2) of the Social Security Act [subsec. (b)(2) of this section]) by not later than 90 days after the date of the enactment of this Act (July 1, 1988)."

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(i)(ii)(B), (C) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title I, General Provisions.

Amendment by section 428(b) of Pub. L. 100–360 effective July 1, 1988, and applicable only with respect to violations occurring on or after such date, see section 428(c) of Pub. L. 100–360, set out as an Effective Date note under section 1320b–10 of this title.

Effective Date of 1987 Amendments


"(1) Except as provided in subparagraph (B), each State shall have 1 year from the date the National Association of Insurance Commissioners adopts the revised NAIC model law and regulations (as changed by this section) to conform the regulatory program established by the State to such revised NAIC model law and regulations.

"(B) In the case of a State which the Secretary of Health and Human Services identifies as—

"(i) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to be changed to meet the requirements of section 1882(c)(3) of the Social Security Act [subsec. (c)(3) of this section], and

"(ii) having a legislature which is not scheduled to meet in 1988, the date specified in this subparagraph is the first day of the first legislative session of the State legislature that begins on or after January 1, 1989, and in which legislation described in clause (i) may be considered.

"(2) The amendment made by subsection (b) [amending this section] shall apply to medicare supplemental policies as of January 1, 1989 (or, if applicable, the date established under subparagraph (B)).

"(3) (A) In general.—The Secretary of Health and Human Services identifies as—

"(i) requiring State legislation (other than legislation appropriating funds) in order for medicare supplemental policies to be changed to meet the requirements of section 1882(c)(3) of the Social Security Act [subsec. (c)(3) of this section], and

"(ii) having a legislature which is not scheduled to meet in 1988 in a legislative session in which such legislation may be considered or which has not enacted such legislation before July 1, 1988,

"(B) No carrier may issue a new or revised medicare supplemental policy under section 1395ss to participate as a PDP sponsor under such part D as a condition for issuing such policy.

"(C) Transition dates.—Except as provided in subparagraph (B), each State shall have 1 year from the date the National Association of Insurance Commissioners adopts the revised NAIC model law and regulations (as changed by this section) to conform the regulatory program established by the State to such revised NAIC model law and regulations.

Section 507(b) of Pub. L. 96–265 provided that: "The amendment made by this section [enacting this section] shall become effective on the date of the enactment of this Act [June 9, 1980], except that the provisions of paragraph (1) of section 1882(d) of the Social Security Act [subsec. (d)(4) of this section] (as added by this section) shall become effective on July 1, 1982."
(42 U.S.C. 1395ss) that meets the requirements of such revised NAIC model law and regulations for coverage effective prior to June 1, 2010. A carrier may continue to offer or issue a medicare supplemental policy under such section that meets the requirements of the NAIC model law and regulations and State law (as in effect prior to the adoption of such revised NAIC model law and regulations) prior to June 1, 2010. Nothing shall preclude carriers from marketing new or revised medicare supplemental policies or certificates that meet the requirements of such revised NAIC model law and regulations on or after the date on which the State conforms the regulatory program established by the State to such revised NAIC model law and regulations."

STUDY OF MEDIGAP POLICIES

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §553(a)], Nov. 29, 1999, 113 Stat. 1358, 1501A–393, provided that:

"(1) In General.—The Comptroller General of the United States (in this section referred to as the ‘Comptroller General’) shall conduct a study of the issues described in paragraph (2) regarding medicare supplemental policies described in section 1882(g)(1) of the Social Security Act (42 U.S.C. 1395ss(g)(1)).

"(2) Issues to be studied.—The issues described in this paragraph are the following:

"(A) The extent to which medicare guarantees for the purposes of applying the provisions of medicare program to the changes made by this Act, or

"(B) The current enrollment levels in each type of medicare supplemental policy.

"(C) The availability of each type of medicare supplemental policy to medicare beneficiaries over age 65½.

"(D) The number and type of medicare supplemental policies offered in each State.

"(E) The average out-of-pocket costs (including premiums) per beneficiary under each type of medicare supplemental policy.

"(3) Report.—Not later than July 31, 2001, the Comptroller General shall submit a report to Congress on the results of the study conducted under this subsection, together with any recommendations for legislation that the Comptroller General determines to be appropriate as a result of such study.

CONFORMING BENEFITS TO CHANGES IN TERMINOLOGY FOR HOSPITAL OUTPATIENT DEPARTMENT COST SHARING

Section 4031(f) of Pub. L. 105–33 provided that: “For purposes of apply [sic] section 1882 of the Social Security Act (42 U.S.C. 1395ss) and regulations referred to in such section as a note above, copayment amounts provided under section 1833(t)(5) of such Act [section 1395ss(t)(5) of this title] with respect to hospital outpatient department services shall be treated under medicare supplemental policies in the same manner as coinsurance with respect to such services.”

TRANSITION PROVISIONS

Pub. L. 110–235, title I, §104(d), May 21, 2008, 122 Stat. 903, provided that:

"(1) In General.—If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the changes made by this section [amending this section], the State regulatory program to the changes made by this section [amending this section] due solely to failure to make such change until the date specified in paragraph (4).

"(2) NAIC STANDARDS.—If, not later than October 31, 2008, the National Association of Insurance Commissioners (in this subsection referred to as the ‘NAIC’) modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act [this section] due solely to failure to make such change until the date specified in paragraph (4), such revised regulation incorporating the modifications shall be considered to be the applicable NAIC model regulation (including the revised NAIC model regulation and the 1991 NAIC Model Regulation) for the purposes of such section.

"(3) SECURITIZATION STANDARDS.—If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the appropriate regulation for the purposes of such section.

"(4) DATE SPECIFIED.—

"(A) IN GENERAL.—Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of—

"(i) the date the State changes its statutes or regulations to conform its regulatory program to the changes made by this section, or

"(ii) July 1, 2009.

"(B) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State which the Secretary identifies as—

"(i) requiring State legislation (other than legislation appropriating funds) to conform its regulatory program to the changes made in this section, but

"(ii) having a legislature which is not scheduled to meet in 2009 in a legislative session in which such legislation may be considered, the date specified in this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after July 1, 2009. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

Section 4031(e) of Pub. L. 105–33 provided that:

"(1) In General.—If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the changes made by this section [amending this section], the State regulatory program shall not be considered to be out of compliance with the requirements of section 1882 of the Social Security Act [this section] due solely to failure to make such change until the date specified in paragraph (4).

"(2) NAIC STANDARDS.—If, within 9 months after the date of the enactment of this Act [Aug. 5, 1997], the National Association of Insurance Commissioners (in this subsection referred to as the ‘NAIC’) modifies its NAIC Model Regulation relating to section 1882 of the Social Security Act [this section] (referred to in such section as the NAIC Model Regulation, as modified pursuant to section 171(m)(2) of the Social Security Act Amendments of 1994 (Public Law 103–422) [set out as a note below] and as modified pursuant to section 171(m)(2) of the Social Security Act Amendments of 1996 (Public Law 104–191) to conform to the amendments made by this section [amending this section]), such revised regulation incorporating the modifications shall be considered to be the applicable NAIC model regulation (including the revised NAIC model regulation and the 1991 NAIC Model Regulation) for the purposes of such section.

"(3) SECURITIZATION STANDARDS.—If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the appropriate Regulation for the purposes of such section.

"(4) DATE SPECIFIED.—

"(A) IN GENERAL.—Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of—
“(i) the date the State changes its statutes or regulations to conform its regulatory program to the changes made by this section, or

(ii) 1 year after the date the NAIC or the Secretary first makes the modifications under paragraph (2) or (3), respectively.

(1) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State which the Secretary identifies as—

(ii) having a legislature which is not scheduled to meet in 1999 in a legislative session in which such legislation may be considered, the date specified in this paragraph is the first day of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after July 1, 1999. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.’’

Section 171(c) of Pub. L. 104–191 provided that:

“(1) NO PENALTIES.—Subject to paragraph (3), no criminal or civil money penalty may be imposed under section 1882(d)(3)(A) of the Social Security Act (subsection (d)(3)(A) of this section) for any act or omission that occurred during the transition period (as defined in paragraph (4)) and that relates to any health insurance policy that is described in clause (iv) or (v) of such section (as amended by subsection (a)).

“(2) LIMITATION ON LEGAL ACTION.—Subject to paragraph (3), no legal action shall be brought or continued in any Federal or State court insofar as such action—

“A includes a cause of action which arose, or which is based on or evidenced by any act or omission which occurred, during the transition period; and

“B relates to the application of section 1882(d)(3)(A) of the Social Security Act to any act or omission with respect to the sale, issuance, or renewal of any health insurance policy that is described in clause (iv) or (v) of such section (as amended by subsection (a)).

“(3) DISCLOSURE CONDITION.—In the case of a policy described in clause (iv) of section 1882(d)(3)(A) of the Social Security Act that is sold or issued on or after the effective date of statements under section 171(d)(3)(C) of the Social Security Act Amendments of 1984 [Pub. L. 98–44, set out below] and before the end of the first calendar quarter beginning after the enactment of this Act [Aug. 21, 1994], paragraphs (1) and (2) shall only apply if disclosure was made in accordance with section 1882(d)(3)(C)(ii) of the Social Security Act (as in effect before the date of the enactment of this Act).

“(4) TRANSITION PERIOD.—In this subsection, the term ‘transition period’ means the period beginning on November 5, 1991, and ending on the date of the enactment of this Act.’’

APPLICABILITY OF DISCLOSURE REQUIREMENT

Section 171(d)(3)(C) of Pub. L. 103–432 provided that:

‘‘The requirement of a disclosure under section 1882(d)(3)(C)(i) of the Social Security Act [subsection (d)(3)(C)(i) of this section] shall not apply to an application made for a policy or plan before 60 days after the date the Secretary of Health and Human Services publishes or promulgates all the statements under section 1882(d)(3)(D) of such Act.’’

STATE REGULATORY PROGRAMS

Section 171(m) of Pub. L. 103–432 provided that:

“(1) IN GENERAL.—If the Secretary of Health and Human Services identifies a State as requiring a change to its statutes or regulations to conform its regulatory program to the changes made by this section [amending this section and sections 1320c–3, 1395b–2, and 1395b–4 of this title, repealing section 1395zz of this title, and enacting and amending provisions set out as notes under this section], the State regulatory program shall not be considered to be out of compliance with the requirements of section 1882 of the Social Security Act [this section] due solely to failure to make such change until the date specified in paragraph (4).

“(2) NAIC STANDARDS.—If, within 6 months after the date of the enactment of this Act [Oct. 31, 1994], the National Association of Insurance Commissioners (in this subsection referred to as the ‘NAIC’) modifies its 1991 NAIC Model Regulation (adopted in July 1991) to conform to the amendments made by this section and to delete from section 156 the exception which begins with ‘unless’, such revised regulation incorporating the modifications shall be considered to be the 1991 Regulation for the purposes of section 1882 of the Social Security Act.

“(3) SECRETARY STANDARDS.—If the NAIC does not make the modifications described in paragraph (2) within the period specified in such paragraph, the Secretary of Health and Human Services shall make the modifications described in such paragraph and such revised regulation incorporating the modifications shall be considered to be the 1991 Regulation for the purposes of section 1882 of the Social Security Act.

“(4) DATE SPECIFIED.—

“A In general.—Subject to subparagraph (B), the date specified in this paragraph for a State is the earlier of—

“(i) the date the State changes its statutes or regulations to conform its regulatory program to the changes made by this section, or

“(ii) 1 year after the date the NAIC or the Secretary first makes the modifications under paragraph (2) or (3), respectively.

“(B) ADDITIONAL LEGISLATIVE ACTION REQUIRED.—In the case of a State which the Secretary identifies as—

“(i) requiring State legislation (other than legislation appropriating funds) to conform its regulatory program to the changes made by this section, or

“(ii) having a legislature which is not scheduled to meet in 1996 in a legislative session in which such legislation may be considered, the date specified in this paragraph for a State is the earlier of—

“(A) the date the Secretary of Health and Human Services publishes or promulgates all the statements under section 1882(d)(3)(C) of the Social Security Act Amendments of 1984 [Pub. L. 98–44, set out below] and before the end of the first calendar quarter beginning after the close of the first legislative session of the State legislature that begins on or after January 1, 1996, for purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature;’’

EVALUATION OF 1990 AMENDMENTS

Section 4358(d) of Pub. L. 101–508 provided that: ‘‘The Secretary of Health and Human Services shall conduct an evaluation of the amendments made by this section [amending this section and section 1320c–3 of this title] and shall report to Congress on such evaluation by not later than January 1, 1996.’’

§ 1395ss–1. Clarification

Any health insurance policy that provides reimbursement for expenses incurred for items and services for which payment may be made under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] but which are not reimbursable by reason of the applicability of deductibles, coinsurance, copayments or other limitations imposed by a Medicare Advantage plan (including a Medicare Advantage private fee-for-service plan) under part C of such title [42 U.S.C. 1395w–21 et seq.] shall comply with the require-
ments of section 1882(o) of the such Act (42 U.S.C. 1395ss(o)).


REFERENCES IN TEXT
The Social Security Act, referred to in text, is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to this subchapter. Part C of title XVIII of the Act is classified to section 1395w–21 et seq. of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION
Section was enacted as part of the Medicare Improvements for Patients and Providers Act of 2008, and not as part of the Social Security Act which comprises this chapter.

§ 1395tt. Hospital providers of extended care services

(a) Hospital facility agreements; reasonable costs of services

(1) Any hospital which has an agreement under section 1395cc of this title may (subject to subsection (b) of this section) enter into an agreement with the Secretary under which its inpatient hospital facilities may be used for the furnishing of services of the type which, if furnished by a skilled nursing facility, would constitute extended care services.

(2)(A) Notwithstanding any other provision of this subchapter, payment to any hospital (other than a critical access hospital) for services furnished under an agreement entered into under this section shall be based upon the reasonable cost of the services as determined under subsection (B),

(B)(i) The reasonable cost of the services consists of the reasonable cost of routine services (determined under clause (ii)) and the reasonable cost of ancillary services (determined under clause (iii)).

(ii) The reasonable cost of routine services furnished during any calendar year by a hospital under an agreement under this section is equal to the product of—

(I) the number of patient-days during the year for which the services were furnished, and

(II) the average reasonable cost per patient-day being the average rate per patient-day paid for routine services during the most recent year for which cost reporting data are available with respect to such services (increased in a compounded manner by the applicable increase for payments for routine service costs of skilled nursing facilities under sub-sections (a) through (d) of section 1395yy of this title for subsequent cost reporting periods and up to and including such calendar year) under this subchapter to freestanding skilled nursing facilities in the region (as defined in section 1395ww(d)(2)(D) of this title) in which the facility is located.

(iii) The reasonable cost of ancillary services shall be determined in the same manner as the reasonable cost of ancillary services provided for inpatient hospital services.

(3) Notwithstanding any other provision of this subchapter, a critical access hospital shall be paid for covered skilled nursing facility services furnished under an agreement entered into under this section on the basis of equal to 101 percent of the reasonable costs of such services (as determined under section 1395x(v) of this title).

(b) Eligible facilities

The Secretary may not enter into an agreement under this section with any hospital unless, except as provided under subsection (g) of this section, the hospital is located in a rural area and has less than 100 beds.

(c) Terms and conditions of facility agreements

An agreement with a hospital under this section shall, except as otherwise provided under regulations of the Secretary, be of the same duration and subject to termination on the same conditions as are agreements with skilled nursing facilities under section 1395cc of this title and shall, where not inconsistent with any provision of this section, impose the same duties, responsibilities, conditions, and limitations, as those imposed under such agreements entered into under section 1395cc of this title; except that no such agreement with any hospital shall be in effect for any period during which the hospital does not have in effect an agreement under section 1395cc of this title. A hospital with respect to which an agreement under this section has been terminated shall not be eligible to enter into a new agreement until a two-year period has elapsed from the termination date.

(d) Post-hospital extended care services

Any agreement with a hospital under this section shall provide that payment for services will be made only for services for which payment would be made as post-hospital extended care services if those services had been furnished by a skilled nursing facility under an agreement entered into under section 1395cc of this title; and any individual who is furnished services, for which payment may be made under an agreement entered into under this section, shall, for purposes of this subchapter (other than this section), be deemed to have received post-hospital extended care services in like manner and to the same extent as if the services furnished to him had been furnished by a skilled nursing facility under an agreement under section 1395cc of this title.

(e) Reimbursement for routine hospital services

During a period for which a hospital has in effect an agreement under this section, in order to allocate routine costs between hospital and long-term care services for purposes of determining payment for inpatient hospital services, the total reimbursement due for routine services from all classes of long-term care patients (including this subchapter, subchapter XIX of this chapter, and private pay patients) shall be subtracted from the hospital’s total routine costs before calculations are made to determine this subchapter reimbursement for routine hospital services.

So in original.
(f) Conditions applicable to skilled nursing facilities

A hospital which enters into an agreement with the Secretary under this section shall be required to meet those conditions applicable to skilled nursing facilities relating to discharge planning and the social services function (and states the requirements to satisfy (1) which are promulgated by the Secretary under section 1395i–3 of this title. Services furnished by such a hospital which would otherwise constitute post-hospital extended care services if furnished by a skilled nursing facility shall be subject to the same requirements applicable to such services when furnished by a skilled nursing facility except for those requirements the Secretary determines are inappropriate in the case of these services being furnished by a hospital under this section.

(g) Agreements on demonstration basis

The Secretary may enter into an agreement under this section on a demonstration basis with any hospital which does not meet the requirements of subsection (b)(1) of this section (read as if the hospital otherwise meets the requirements of this section).


AMENDEMENTS


1999—Subsec. (a)(1). Pub. L. 106–113, § 1000(a)(6) (title IV, § 403(f)(2)), struck out “, or during which there is in effect for the hospital a waiver under subparagraph (A) of the last sentence of section 1395yy of this title” before the period at end of first sentence.

Subsec. (d). Pub. L. 106–113, § 1000(a)(6) (title IV, § 408(b)), struck out “(1)” before “Any agreement with a hospital” and struck out pars. (2) and (3), which related to limiting payments under extended care service agreements pursuant to this section to hospitals with more than 49 beds where skilled nursing facilities were available or where such payments exceeded a designated maximum.

1997—Subsec. (a)(2)(B)(II), Pub. L. 106–33 inserted “subsections (a) through (d) of” before “section 1395yy”.

1996—Subsec. (a)(2)(B)(II). Pub. L. 105–33 substituted “the most recent year for which cost reporting data are available with respect to such services (increased in a compounded manner by the applicable increase for payments for routine service costs of skilled nursing facilities under section 1395yy of this title for subsequent cost reporting periods and up to and including such calendar year) under this subchapter to free-standing skilled nursing facilities in the region (as defined in section 1395ww(d)(2)(B) of this title) in which the facility is located.” for “the previous calendar year” and all that followed thereon, which was executed by making the substitution for “the previous calendar year under the State plan (of the State in which the hospital is located) under subchapter XIX of this chapter to skilled nursing facilities located in the State and which meet the requirements specified in section 1396a(a)(28) of this title, or, in the case of a hospital located in a State which does not have such a State plan, the average rate per patient-day paid for routine services during the previous calendar year under this subchapter to skilled nursing facilities in such State.”

1995—Subsec. (d)(1), (f), Pub. L. 104–234 repealed Pub. L. 100–360, § 104(d)(6), 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 notes below.


1991—Subsec. (d)(3). Pub. L. 100–360, § 411(b)(4)(D), inserted before period at end “, except that such payment shall continue to be made in the period for those patients who are receiving extended care services at the time the hospital reaches the limit specified in this paragraph”.


1986—Subsec. (b)(3). Pub. L. 100–360, § 411(b)(4)(D), struck out before period at end “, except that such payment shall continue to be made in the period for those patients who are receiving extended care services at the time the hospital reaches the limit specified in this paragraph”.


EFFECTIVE DATE OF 2003 AMENDMENT


EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, § 1(a)(6) (title II, § 203(c)), Dec. 21, 2000, 114 Stat. 2763, 2763A–482, provided that: “The amendments made by this section [amending this section and section 1395yy of this title] shall apply to cost report-
ing periods beginning on or after the date of the enactment of this Act [Dec. 21, 2000].”

**Effective Date of 1999 Amendment**

Pub. L. 106–113, div. B, §100(a)(6) [title IV, §408(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–375, provided that:

“The amendments made by this section [amending this section] shall apply to services furnished on or after October 1, 1999, except as otherwise specifically provided in section 1395yy(e)(2)(E) of the Social Security Act (42 U.S.C. 1395yy(e)(2)(E)) for payments for covered skilled nursing facility services under the medicare program.”

**Effective Date of 1997 Amendment**

Amendment by Pub. L. 105–33 applicable to items and services furnished after July 1, 1998, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395i–3 of this title.

**Effective Date of 1990 Amendment**

Section 4008(j)(4) of Pub. L. 101–508 provided that:

“The amendments made by paragraph (1) [amending this section] shall apply to services furnished on or after October 1, 1990.”

**Effective Date of 1989 Amendment**


**Effective Date of 1988 Amendments**

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 6208(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 104(d)(6) of Pub. L. 100–360 effective Jan. 1, 1989, except as otherwise provided, and applicable to inpatient hospital deductible for 1989 and succeeding years, to care and services furnished on or after Jan. 1, 1989, to premiums for January 1989 and succeeding months, and to blood or blood cells furnished on or after Jan. 1, 1989, see section 104(a) of Pub. L. 100–360, set out as a note under section 1395cc of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(b)(4)(D), (1)(C) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–203, set out as a reference to OBRA; Effective Date note under section 106 of Title I, General Provisions.

**Effective Date of 1987 Amendment**

Section 4005(b)(3) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(b)(4)(E), as added by Pub. L. 100–485, title VI, §608(b)(18)(C), Oct. 13, 1988, 102 Stat. 2419, directed Secretary of Health and Human Services to report to Congress, not later than Feb. 1, 1989, concerned the proportion of admissions to hospitals for extended care services under this section which are denied or approved by a peer review organization, and recommendations for methods of encouraging hospitals that have a low occupancy rate, are eligible to enter (but have not entered) into an agreement under this section, and are located in areas with a need for additional providers of extended care services, to enter into such agreements.

**Report on Hospital Admissions for Extended Care Services**


**Hold Harmless for Amendment by Pub. L. 101–508**

Section 4008(j)(2) of Pub. L. 101–508 provided that: “If, as a result of the amendment made by paragraph (1) [amending this section], the reasonable cost of routine services furnished by a hospital during a calendar year (as determined under section 1395yy(e)(2)(E) of the Social Security Act [this section]) is less than the reasonable cost of such services determined under such section for the previous calendar year, the reasonable cost of such services furnished by the hospital during the calendar year under such section shall be equal to the reasonable cost determined under such section for the previous calendar year.”

**Swing Beds Certified Prior to May 1, 1987**

Section 4008(j)(3) of Pub. L. 101–508 provided that: “Notwithstanding the requirement of section 1853(b)(1) of the Social Security Act [subsec. (b)(1) of this section] that the Secretary may not enter into an agreement under such section with a hospital that is not located in a rural area, any agreement entered into under such section on or before May 1, 1987, between the Secretary of Health and Human Services and a hospital located in an urban area shall remain in effect.”

**Report of Hospital Admissions for Extended Care Services**

Section 4005(b)(3) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(b)(4)(E), as added by Pub. L. 100–485, title VI, §608(b)(18)(C), Oct. 13, 1988, 102 Stat. 2419, directed Secretary of Health and Human Services to report to Congress, not later than Feb. 1, 1989, concerning the proportion of admissions to hospitals for extended care services under this section which are denied or approved by a peer review organization, and recommendations for methods of encouraging hospitals that have a low occupancy rate, are eligible to enter (but have not entered) into an agreement under this section, and are located in areas with a need for additional providers of extended care services, to enter into such agreements.

**Report on Hospital Providers of Extended Care, Skilled Nursing, and Intermediate Care Services**

Section 906(c) of Pub. L. 96–499 directed Secretary of Health and Human Services, within three years after Dec. 5, 1980, to submit to Congress a report evaluating programs established by the amendments made by this section (enacting this section and section 1395yy of this title), including in such report an analysis of the extent and effect of the agreements under such programs on availability and effective and economical provision of long-term care services, whether such programs should be continued, the results of any demonstration projects conducted under such programs, and whether eligibility to participate in such programs should be extended to other hospitals, regardless of bed size or geographic location, where there is a shortage of long-term care beds.

§ 1395uu. Payments to promote closing or conversion of underutilized hospital facilities

**(a) Transitional allowances; procedures applicable**

Any hospital may file an application with the Secretary (in such form and including such data and information as the Secretary may require) for establishment of a transitional allowance under this subchapter with respect to the closing or conversion of an underutilized hospital facility. The Secretary also may establish procedures, consistent with this section, by which a hospital, before undergoing an actual closure or conversion of a hospital facility, can have a determination made as to whether or not it will be eligible for a transitional allowance under this.
section with respect to such closure or conversion.

(b) Allowable costs as transitional allowances; findings and determinations

If the Secretary finds, after consideration of an application under subsection (a) of this section, that—

(1) the hospital's closure or conversion—

(A) is formally initiated after September 30, 1981,

(B) is expected to benefit the program under this subchapter by (i) eliminating excess bed capacity, (ii) discontinuing an underutilized service for which there are adequate alternative sources, or (iii) substituting for the underutilized service some other service which is needed in the area, and

(C) is consistent with the findings of an appropriate health planning agency and with any applicable State program for reduction in the number of hospital beds in the State, and

(2) in the case of a complete closure of a hospital—

(A) the hospital is a private nonprofit hospital or a local governmental hospital, and

(B) the closure is not for replacement of the hospital,

the Secretary may include as an allowable cost in the hospital's reasonable cost (for the purpose of making payments to the hospital under this subchapter) an amount (in this section referred to as a "transitional allowance"), as provided in subsection (c) of this section.

(c) Factors determinative of transitional allowance

(1) Each transitional allowance established shall be reasonably related to the prior or prospective use of the facility involved under this subchapter and shall recognize—

(A) in the case of a facility conversion or closure (other than a complete closure of a hospital)—

(i) in the case of a private nonprofit or local governmental hospital, that portion of the hospital's costs attributable to capital assets of the facility which have been taken into account in determining reasonable cost for purposes of determining the amount of payment to the hospital under this subchapter, and

(ii) in the case of any hospital, transitional operating cost increases related to the conversion or closure to the extent that such operating costs exceed amounts ordinarily reimbursable under this subchapter; and

(B) in the case of complete closure of a hospital, the outstanding portion of actual debt obligations previously recognized as reasonable for purposes of reimbursement under this subchapter, less any salvage value of the hospital.

(2) A transitional allowance shall be for a period (not to exceed 20 years) specified by the Secretary, except that, in the case of a complete closure described in paragraph (1)(B), the Secretary may provide for a lump-sum allowance where the Secretary determines that such a one-time allowance is more efficient and economical.

(3) A transitional allowance shall take effect on a date established by the Secretary, but not earlier than the date of completion of the closure or conversion concerned.

(4) A transitional allowance shall not be considered in applying the limits to costs recognized as reasonable pursuant to the third sentence of subparagraph (A) and subparagraph (L)(i) of section 1395x(v)(1) of this title, or in determining whether the reasonable cost exceeds the customary charges for a service for purposes of determining the amount to be paid to a provider pursuant to sections 1395f(b) and 1395f(a)(2) of this title.

(d) Hearing to review determination

A hospital dissatisfied with a determination of the Secretary on its application under this section may obtain an informal or formal hearing, at the discretion of the Secretary, by filing (in such form and within such time period as the Secretary establishes) a request for such a hearing. The Secretary shall make a final determination on such application within 30 days after the last day of such hearing.


Amendments

Effective Date of 1982 Amendment
Amendment by Pub. L. 97–248 effective as if originally included as part of this section as this section was enacted by the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, see section 128(e)(2) of Pub. L. 97–248, set out as a note under section 1395x of this title.

Effective Date
Section 2101(c) of Pub. L. 97–35 provided that: "The amendment made by subsection (a) [enacting this section and amending section 1396b of this title] shall apply only to services furnished by a hospital during any accounting year beginning on or after October 1, 1981."

Payments To Promote Closure and Conversion of Underutilized Hospital Facilities
Pub. L. 98–369, div. B, title III, §2353, July 18, 1984, 98 Stat. 1099, directed Secretary of Health and Human Services to carry out a study and report to Congress prior to Mar. 31, 1986, on modifications required in this section in order to conform the closure and conversion program authorized in that section to the prospective payment system under section 1800w(h)(4) of this title, so as to provide assistance to hospitals which may have particular problems in converting facilities (or parts thereof) from acute care to less intensive care or in closing facilities (or parts thereof), such report to include recommendations as to how, and whether, implementation of this section as modified may result in reductions in total hospital inpatient costs and total ex-
penditures under this subchapter, and prohibited from implementing this section prior to Mar. 31, 1985.

Section 2101(b) of Pub. L. 97–35 prohibited Secretary of Health and Human Services from establishing under this section transitional allowances with respect to more than 50 hospitals prior to Jan. 1, 1984, and directed Secretary to evaluate effectiveness of program of transitional allowances established under this section and, not later than Jan. 1, 1983, report to Congress on such evaluation and include in such report such recommendations for such legislative changes as deemed appropriate.

§ 1395vv. Withholding payments from certain medicaid providers

(a) Adjustments by Secretary

The Secretary may adjust, in accordance with this section, payments under parts A and B to any institution which has in effect an agreement with the Secretary under section 1395cc of this title, and any person who has accepted payment on the basis of an assignment under section 1395vv. Withholding payments from certain medicaid providers

(b) Implementing regulations; notice, opportunity to be heard, etc.

The Secretary shall by regulation provide procedures for implementation of this section, which procedures shall—

(1) assure that the authority under this section is exercised only on behalf of a State agency which demonstrates to the Secretary’s satisfaction that it has provided adequate notice of a determination or of a need for information, and an opportunity to appeal such determination or to provide such information;

(2) determine the amount of the payment to which the institution or person would otherwise be entitled under this subchapter which shall be treated as a setoff against overpayments made under the State plan, or (B) has been unable to collect the information necessary to enable it to determine the amount (if any) of the overpayments made to such institution or person under the State plan.

(c) Payment to States of amounts recovered

Notwithstanding any other provision of this chapter, from the trust funds established under sections 1395l and 1395t of this title, as appropriate, the Secretary shall pay to the appropriate State agency amounts recovered under this section to offset the State agency’s overpayment under subchapter XIX of this chapter. Such payments shall be accounted for by the State agency as recoveries of overpayments under the State plan.


§ 1395ww. Payments to hospitals for inpatient hospital services

(a) Determination of costs for inpatient hospital services; limitations; exemptions; “operating costs of inpatient hospital services” defined

(1)(A)(i) The Secretary, in determining the amount of the payments that may be made under this subchapter with respect to operating costs of inpatient hospital services (as defined in paragraph (4)) shall not recognize as reasonable (in the efficient delivery of health services) costs for the provision of such services by a hospital for a cost reporting period to the extent such costs exceed the applicable percentage (as determined under clause (ii)) of the average of such costs for all hospitals in the same grouping as such hospital for comparable time periods.

(ii) For purposes of clause (i), the applicable percentage for hospital cost reporting periods beginning—

(I) on or after October 1, 1982, and before October 1, 1983, is 120 percent;

(II) on or after October 1, 1983, and before October 1, 1984, is 115 percent; and

(III) on or after October 1, 1984, is 110 percent.

(B)(i) For purposes of subparagraph (A) the Secretary shall establish case mix indexes for all short-term hospitals, and shall set limits for each hospital based upon the general mix of types of medical cases with respect to which such hospital provides services for which payment may be made under this subchapter.

(ii) The Secretary shall set such limits for a cost reporting period of a hospital—

(I) by updating available data for a previous period to the immediate preceding cost reporting period by the estimated average rate of change of hospital costs industry-wide, and

(II) by projecting for the cost reporting period for which this section is in effect.

(C) The limitation established under subparagraph (A) for any hospital shall in no event be lower than the allowable operating costs of inpatient hospital services (as defined in paragraph (4)) recognized under this subchapter for such hospital for such hospital’s last cost reporting period prior to the hospital’s first cost reporting period for which this section is in effect.

(D) Subparagraph (A) shall not apply to cost reporting periods beginning on or after October 1, 1983.

(2) The Secretary shall provide for such exemptions from, and exceptions and adjustments to, the limitation established under paragraph (1)(A) as he deems appropriate, including those which he deems necessary to take into account—
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(A) the special needs of sole community hospitals, of new hospitals, of risk based health maintenance organizations, and of hospitals which provide atypical services or essential community services, and to take into account extraordinary circumstances beyond the hospital's control, medical and paramedical education costs, significantly fluctuating population in the service area of the hospital, and unusual labor costs,

(B) the special needs of psychiatric hospitals and of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of this subchapter, and

(C) a decrease in the inpatient hospital services that a hospital provides and that are customarily provided directly by similar hospitals which results in a significant distortion in the operating costs of inpatient hospital services.

(3) The limitation established under paragraph (1)(A) shall not apply with respect to any hospital which—

(A) is located outside of a standard metropolitan statistical area, and

(B)(i) has less than 50 beds, and

(ii) was in operation and had less than 50 beds on September 3, 1982.

(4) For purposes of this section, the term "operating costs of inpatient hospital services" includes all routine operating costs, ancillary service operating costs, and special care unit operating costs, a return on equity capital, other capital-related costs (as defined by the Secretary) to individuals with hemophilia. In applying the first sentence of this paragraph, the term "other services related to the admission" includes all services that are not diagnostic services (including clinical diagnostic laboratory tests) or other services related to the admission (as defined by the Secretary). Such term does not include costs of approved educational activities, a return on equity capital, other capital-related costs (as defined by the Secretary for periods before October 1, 1987), or costs with respect to administering blood clotting factors to individuals with hemophilia. In applying the first sentence of this paragraph, the term "other services related to the admission" includes all services that are not diagnostic services (other than ambulance and maintenance renal dialysis services) for which payment may be made under this subchapter that are provided by a hospital (or an entity wholly owned or operated by the hospital) to a patient—

(A) on the date of the patient's inpatient admission; or

(B) during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of such admission unless the hospital demonstrates (in a form and manner, and at a time, specified by the Secretary) that such services are not related (as determined by the Secretary) to such admission.

(b) Computation of payment; definitions; exemptions; adjustments

(1) Notwithstanding section 1395f(b) of this title but subject to the provisions of section 1395e of this title, if the operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section) of a hospital (other than a subsection (d) hospital, as defined in subsection (d)(1)(B) of this section and other than a rehabilitation facility described in subsection (j)(1) of this section) for a cost reporting period subject to this paragraph—

(A) are less than or equal to the target amount (as defined in paragraph (3)) for that hospital for that period, the amount of the payment with respect to such operating costs payable under part A of this subchapter on a per discharge or per admission basis (as the case may be) shall be equal to the amount of such operating costs, plus—

(i) 15 percent of the amount by which the target amount exceeds the amount of the operating costs, or

(ii) 2 percent of the target amount, whichever is less;

(B) are greater than the target amount but do not exceed 110 percent of the target amount, the amount of the payment with respect to those operating costs payable under part A of this subchapter on a per discharge or per admission basis (as the case may be) shall be equal to (i) the target amount, plus (ii) in the case of cost reporting periods beginning on or after October 1, 1991, an additional amount equal to 50 percent of the amount by which the operating costs exceed 110 percent of the target amount (except that such additional amount may not exceed 10 percent of the target amount) after any exceptions or adjustments are made to such target amount for the cost reporting period;

plus the amount, if any, provided under paragraph (2), except that in no case may the amount payable under this subchapter (other than on the basis of a DRG prospective payment rate determined under subsection (d) of this section) with respect to operating costs of inpatient hospital services exceed the maximum amount payable with respect to such costs pursuant to subsection (a) of this section.

(2)(A) Except as provided in subparagraph (B), in addition to the payment computed under paragraph (1), in the case of an eligible hospital (described in subparagraph (B)) for a cost reporting period beginning on or after October 1, 1997, the amount of payment on a per discharge basis under paragraph (1) shall be increased by the lesser of—

(i) 50 percent of the amount by which the operating costs are less than the expected costs (as defined in subparagraph (D)) for the period; or
(ii) 1 percent of the target amount for the period.

(B) For purposes of this paragraph, an “eligible hospital” means with respect to a cost reporting period, a hospital—

(i) that has received payments under this subsection for at least 3 full cost reporting periods before that cost reporting period, and

(ii) whose operating costs for the period are less than the least of its target amount, its trended costs (as defined in subparagraph (C)), or its expected costs (as defined in subparagraph (D)) for the period.

(C) For purposes of subparagraph (B)(ii), the term “trended costs” means for a hospital cost reporting period ending in a fiscal year—

(i) in the case of a hospital for which its cost reporting period ending in fiscal year 1996 was its third or subsequent full cost reporting period for which it receives payments under this subsection, the lesser of the operating costs or target amount for that hospital for its cost reporting period ending in fiscal year 1996, or

(ii) in the case of any other hospital, the operating costs for that hospital for its third full cost reporting period for which it receives payments under this subsection,

increased (in a compounded manner) for each succeeding fiscal year (through the fiscal year involved) by the market basket percentage increase for the fiscal year.

(D) For purposes of this paragraph, the term “expected costs”, with respect to the cost reporting period ending in a fiscal year, means the lesser of the operating costs of inpatient hospital services or target amount per discharge for the previous cost reporting period updated by the market basket percentage increase (as defined in paragraph (3)(B)(iii)) for the fiscal year.

(E)(i) In the case of an eligible hospital that is a hospital or unit that is within a class of hospital described in clause (ii) with a 12-month cost reporting period beginning before November 29, 1999, in determining the amount of the increase under subparagraph (A), the Secretary shall substitute for the percentage of the target amount applicable under subparagraph (A) (ii)—

(I) for a cost reporting period beginning on or after October 1, 2000, and before September 30, 2001, 1.5 percent; and

(II) for a cost reporting period beginning on or after October 1, 2001, and before September 30, 2002, 2 percent.

(ii) For purposes of clause (i), each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) of this section and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (iv) of such subsection.

(3)(A) Except as provided in subparagraph (C) and succeeding subparagraphs, and in paragraph (7)(A)(ii), for purposes of this subsection, the term “target amount” means, with respect to a hospital for a particular 12-month cost reporting period—

(i) in the case of the first such reporting period for which this subsection is in effect, the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section) recognized under this subchapter for such hospital for the preceding 12-month cost reporting period, and

(ii) in the case of a later reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B) for that particular cost reporting period.

(B)(i) For purposes of subsection (d) of this section and subsection (j) of this section for discharges occurring during a fiscal year, the “applicable percentage increase” shall be—

(I) for fiscal year 1986, ½ percent,

(II) for fiscal year 1987, 1.15 percent,

(III) for fiscal year 1988, 3.0 percent for hospitals located in a rural area, 1.5 percent for hospitals located in a large urban area (as defined in subsection (d)(2)(D) of this section), and 1.0 percent for hospitals located in other urban areas,

(IV) for fiscal year 1989, the market basket percentage increase minus 1.5 percent for hospitals located in a rural area, the market basket percentage increase minus 2.0 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 2.5 percentage points for hospitals located in other urban areas,

(V) for fiscal year 1990, the market basket percentage increase plus 4.22 percentage points for hospitals located in a rural area, the market basket percentage increase plus 0.12 percentage points for hospitals located in a large urban area, and the market basket percentage increase minus 0.53 percentage points for hospitals located in other urban areas,

(VI) for fiscal year 1991, the market basket percentage increase minus 2.0 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.7 percentage point for hospitals located in a rural area,

(VII) for fiscal year 1992, the market basket percentage increase minus 1.6 percentage points for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.6 percentage point for hospitals located in a rural area,

(VIII) for fiscal year 1993, the market basket percentage increase minus 1.55 percentage point for hospitals in a large urban or other urban area, and the market basket percentage increase minus 0.55 for hospitals located in a rural area,

(IX) for fiscal year 1994, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and the market basket percentage increase minus 1.0 percentage point for hospitals located in a rural area,

(X) for fiscal year 1995, the market basket percentage increase minus 2.5 percentage points for hospitals located in a large urban or other urban area, and such percentage increase for hospitals located in a rural area as

So in original. Probably should be followed by “percentage point”.

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will provide for the average standardized amount determined under subsection (d)(3)(A) of this section for hospitals located in a rural area being equal to such average standardized amount for hospitals located in an urban area (other than a large urban area).

(XI) for fiscal year 1996, the market basket percentage increase minus 2.0 percentage points for hospitals in all areas,

(XII) for fiscal year 1997, the market basket percentage increase minus 0.5 percentage point for hospitals in all areas,

(XIII) for fiscal year 1998, 0 percent,

(XIV) for fiscal year 1999, the market basket percentage increase minus 1.9 percentage points for hospitals in all areas,

(XV) for fiscal year 2000, the market basket percentage increase minus 1.8 percentage points for hospitals in all areas,

(XVI) for fiscal year 2001, the market basket percentage increase for hospitals in all areas,

(XVII) for fiscal year 2002, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XVIII) for fiscal year 2003, the market basket percentage increase minus 0.55 percentage points for hospitals in all areas,

(XIX) for each of fiscal years 2004 through 2006, subject to clause (vii), the market basket percentage increase for hospitals in all areas; and

(XX) for each subsequent fiscal year, subject to clauses (viii), (ix), (xi), and (xii), the market basket percentage increase for hospitals in all areas.

(ii) For purposes of subparagraphs (A) and (E), the “applicable percentage increase” for 12-month cost reporting periods beginning during—

(I) fiscal year 1986, is 0.5 percent,

(II) fiscal year 1987, is 1.15 percent,

(III) fiscal year 1988, is the market basket percentage increase in fiscal year 1988, which the hospital’s allowable operating costs of inpatient hospital services recognized under this subchapter for the cost reporting period beginning in fiscal year 1988 exceeds the hospital’s target amount (as determined under subparagraph (A)) for such cost reporting period, increased for each fiscal year (beginning with fiscal year 1990) by the sum of any of the hospital’s applicable reductions under this subchapter for previous fiscal years; and

(IV) for fiscal years 1994 through 1997, is the market basket percentage increase

(V) fiscal years 1994 through 1997, is the market basket percentage increase minus 0.5 percentage points (adjusted to exclude any portion of a cost reporting period beginning during fiscal year 1994 by the sum of any of the hospital’s applicable reductions under this subchapter for previous fiscal years)

(vi) For purposes of clause (ii)(V)—

(I) a hospital’s “update adjustment percentage” for a fiscal year is the percentage by which the hospital’s allowable operating costs of inpatient hospital services recognized under this subchapter for the cost reporting period beginning in fiscal year 1990 exceeds the hospital’s target amount (as determined under subparagraph (A)) for such cost reporting period, increased for each fiscal year (beginning with fiscal year 1994) by the sum of any of the hospital’s applicable reductions under this subchapter for previous fiscal years; and

(II) the “applicable reduction” with respect to a hospital for a fiscal year is the lesser of 1 percentage point or the percentage point difference between 10 percent and the hospital’s update adjustment percentage for the fiscal year.

(vii) For purposes of clause (ii)(VII) for a fiscal year, if a hospital’s allowable operating costs of inpatient hospital services recognized under this subchapter for the most recent cost reporting period for which information is available—

(I) is equal to, or exceeds, 110 percent of the hospital’s target amount (as determined under subparagraph (A)) for such cost reporting period, the applicable update factor specified under this clause is the market basket percentage;

(II) exceeds 100 percent, but is less than 110 percent, of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 0.25 percentage points for each percentage point by which such allowable operating costs (expressed as a percentage of such target amount) is less than 110 percent of such target amount;

(III) is equal to, or less than 100 percent, but exceeds ½ of such target amount for the hos-
hospital, the applicable update factor specified under this clause is 0 percent or, if greater, the market basket percentage minus 2.5 percentage points; or

(IV) does not exceed \( \frac{3}{4} \) of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent.

(vii)(I) For purposes of clause (i)(XIX) for fiscal years 2005 and 2006, in a case of a subsection (d) hospital that does not submit data to the Secretary in accordance with subclause (II) with respect to such a fiscal year, the applicable percentage increase under such clause for such fiscal year shall be reduced by 0.4 percentage points. Such reduction shall apply only with respect to the fiscal year involved, and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i)(XIX) for a subsequent fiscal year.

(II) For fiscal years 2005 and 2006, each subsection (d) hospital shall submit to the Secretary quality data (for a set of 10 indicators established by the Secretary as of November 1, 2003) that relate to the quality of care furnished by the hospital in inpatient settings in a form and manner, and at a time, specified by the Secretary for purposes of this clause, but with respect to fiscal year 2005, the Secretary shall provide for a 30-day grace period for the submission of data by a hospital.

(viii)(I) For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced by 2.0 percentage points (or, beginning with fiscal year 2015, by one-quarter of such applicable percentage increase (determined without regard to clause (ix), (xi), or (xii))). Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year, and the Secretary and the Medicare Payment Advisory Commission shall carry out the requirements under section 5001(b) of the Deficit Reduction Act of 2005.

(II) Each subsection (d) hospital shall submit data on measures selected under this clause to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this clause. The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o).

(III) The Secretary shall expand, beyond the measures specified under clause (vii)(II) and consistent with the succeeding subclauses, the set of measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in inpatient settings.

(IV) Effective for payments beginning with fiscal year 2007, in expanding the number of measures under subclause (III), the Secretary shall begin to adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences under section 238(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(V) Effective for payments for fiscal years 2008 through 2012, the Secretary shall add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

(VI) For purposes of this clause and clause (vii), the Secretary may replace any measures or indicators in appropriate cases, such as where all hospitals are effectively in compliance or the measures or indicators have been subsequently shown not to represent the best clinical practice.

(VII) The Secretary shall establish procedures for making information regarding measures submitted under this clause available to the public. Such procedures shall ensure that a hospital has the opportunity to review the data that are to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures of process, structure, outcome, patients’ perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(VIII) Effective for payments beginning with fiscal year 2013, with respect to quality measures for outcomes of care, the Secretary shall provide for such risk adjustment as the Secretary determines to be appropriate to maintain incentives for hospitals to treat patients with severe illnesses or conditions.

(X) To the extent practicable, the Secretary shall, with input from consensus organizations and other stakeholders, take steps to ensure that the measures specified by the Secretary under this clause are coordinated and aligned with quality measures applicable to—

(aa) physicians under section 1395w–4(k) of this title; and

(bb) other providers of services and suppliers under this subchapter.

(XI) The Secretary shall establish a process to validate measures specified under this clause as appropriate. Such process shall include the auditing of a number of randomly selected hospitals sufficient to ensure validity of the reporting program under this clause as a whole and shall provide a hospital with an opportunity to appeal the validation of measures reported by such hospital.
(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(A)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period for such fiscal year, three-quarters of the applicable percentage increase otherwise applicable under clause (i) (determined without regard to clause (viii), (xi), or (xii)) for such fiscal year shall be reduced by 33% percent for fiscal year 2015, 66% percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

(II) The Secretary may, on a case-by-case basis, exempt a subsection (d) hospital from the application of subclause (I) with respect to a fiscal year if the Secretary determines, subject to annual renewal, that requiring such hospital to be a meaningful EHR user during such fiscal year would result in significant hardship, such as in the case of a hospital in a rural area without sufficient Internet access. In no case may a hospital be granted an exemption under this subclause for more than 5 years.

(III) For fiscal year 2015 and each subsequent fiscal year, a State in which hospitals are paid for services under section 1395f(b)(3) of this title shall adjust the payments to each subsection (d) hospital in the State that is not a meaningful EHR user (as defined in subsection (n)(3)) in a manner that is designed to result in an aggregate reduction in payments to hospitals in the State that is equivalent to the aggregate reduction that would have occurred if payments had been reduced to each subsection (d) hospital in the State in a manner comparable to the reduction under the previous provisions of this clause. The State shall report to the Secretary the methodology it will use to make the payment adjustment under the previous sentence.

(IV) For purposes of this clause, the term "EHR reporting period" means, with respect to a fiscal year, any period (or periods) as specified by the Secretary.

(x)(I) The Secretary shall develop standard Internet website reports tailored to meet the needs of various stakeholders such as hospitals, patients, researchers, and policymakers. The Secretary shall seek input from such stakeholders in determining the type of information that is useful and the formats that best facilitate the use of the information.

(II) The Secretary shall modify the Hospital Compare Internet website to make the use and navigation of that website readily available to individuals accessing it.

(xii)(I) For 2012 and each subsequent fiscal year, after determining the applicable percentage increase described in clause (i) and after application of clauses (viii) and (ix), such percentage increase shall be reduced by the productivity adjustment described in subclause (II).

(II) The productivity adjustment described in this subclause, with respect to a percentage, factor, or update for a fiscal year, year, cost reporting period, or other annual period, is a productivity adjustment equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

(III) The application of subclause (I) may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(xii) After determining the applicable percentage increase described in clause (i), and after application of clauses (viii), (ix), and (xii), the Secretary shall reduce such applicable percentage increase—

(I) for each of fiscal years 2010 and 2011, by 0.25 percentage point;

(II) for each of fiscal years 2012 and 2013, by 0.1 percentage point;

(III) for fiscal year 2014, by 0.3 percentage point;

(IV) for each of fiscal years 2015 and 2016, by 0.2 percentage point; and

(V) for each of fiscal years 2017, 2018, and 2019, by 0.75 percentage point.

The application of this clause may result in the applicable percentage increase described in clause (i) being less than 0.0 for a fiscal year, and may result in payment rates under this section for a fiscal year being less than such payment rates for the preceding fiscal year.

(C) In the case of a hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii) of this section), subject to subparagraphs (I) and (L), the term "target amount" means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section) recognized for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the "base cost reporting period") preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period,

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), or
(iv) with respect to discharges occurring in fiscal year 1995 and each subsequent fiscal year, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital’s cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(D) For cost reporting periods ending on or before September 30, 1994, and for discharges occurring on or after October 1, 1997, and before October 1, 2012, in the case of a hospital that is a medicare-dependent, small rural hospital (as defined in subsection (d)(5)(G) of this section), subject to subparagraph (K), the term “target amount” means—

(i) with respect to the first 12-month cost reporting period in which this subparagraph is applied to the hospital—

(I) the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section) recognized under this subchapter for the hospital for the 12-month cost reporting period (in this subparagraph referred to as the “base cost reporting period”) preceding the first cost reporting period for which this subsection was in effect with respect to such hospital, increased (in a compounded manner) by—

(II) the applicable percentage increases applied to such hospital under this paragraph for cost reporting periods after the base cost reporting period and up to and including such first 12-month cost reporting period, or

(ii) with respect to a later cost reporting period beginning before fiscal year 1994, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(iv) for discharges occurring in the fiscal year in which that later cost reporting period begins,

(iii) with respect to discharges occurring in fiscal year 1994, the target amount for the cost reporting period beginning in fiscal year 1993 increased by the applicable percentage increase under subparagraph (B)(iv), and

(iv) with respect to discharges occurring during fiscal year 1998 through fiscal year 2012, the target amount for the preceding year increased by the applicable percentage increase under subparagraph (B)(iv).

There shall be substituted for the base cost reporting period described in clause (i) a hospital’s cost reporting period (if any) beginning during fiscal year 1987 if such substitution results in an increase in the target amount for the hospital.

(E) In the case of a hospital described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(II) The Secretary shall compute the averages of the amounts determined under subparagraph (B)(iv) for each cost reporting period by the applicable percentage increase under subparagraph (B)(iv) for each subsequent cost reporting period up to the cost reporting period described in clause (i).

(III) The Secretary shall identify among such 5 cost reporting periods the cost reporting periods for which the amount determined under subclause (II) is the highest, and the lowest.

(IV) The Secretary shall compute the averages of the amounts determined under subclause (II) for the 3 cost reporting periods not identified under subclause (III).

(iii) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) of this section and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.
(III) Hospitals described in clause (iii) of such subsection.

(IV) Hospitals described in clause (iv) of such subsection.

(V) Hospitals described in clause (v) of such subsection.

(G)(i) In the case of a qualified long-term care hospital (as defined in clause (ii)) that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, the target amount for the hospital’s 12-month cost reporting period beginning during fiscal year 1997 is equal to the allowable operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section) recognized under this subchapter for the hospital for the 12-month cost reporting period beginning during fiscal year 1996, increased by the applicable percentage increase for the cost reporting period beginning during fiscal year 1997.

(ii) In clause (i), a “qualified long-term care hospital” means, with respect to a cost reporting period, a hospital described in clause (iv) of subsection (d)(1)(B) of this section during each of the 2 cost reporting periods for which the Secretary has the most recent settled cost reports as of August 5, 1997, for each of which—

(I) the hospital’s allowable operating costs of inpatient hospital services recognized under this subchapter exceeded 115 percent of the hospital’s target amount, and

(II) the hospital would have a disproportionate patient percentage of at least 75 percent (as determined by the Secretary under subsection (d)(5)(F)(vi) of this section) if the hospital were a subsection (d) hospital.

(H)(i) In the case of a hospital or unit that is within a class of hospital described in clause (iv), for a cost reporting period beginning during fiscal years 1998 through 2002, the target amount for such a hospital or unit may not exceed the amount as updated up to or for such cost reporting period under clause (ii).

(ii)(I) In the case of a hospital or unit that is within a class of hospital described in clause (iv), the Secretary shall estimate the 75th percentile of the target amounts for such hospitals within such class for cost reporting periods ending during fiscal year 1996, as adjusted under clause (iii).

(ii)(II) The Secretary shall update the amount determined under subclause (I), for each cost reporting period after the cost reporting period described in such subclause and up to the first cost reporting period beginning on or after October 1, 1997, by a factor equal to the market basket percentage change.

(III) Hospitals described in clause (iii) of such subsection.

(IV) For purposes of this subparagraph, each of the following shall be treated as a separate class of hospital:

(I) Hospitals described in clause (i) of subsection (d)(1)(B) of this section and psychiatric units described in the matter following clause (v) of such subsection.

(II) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(III) Hospitals described in clause (iv) of such subsection.

(I)(i) Subject to subparagraph (L), for cost reporting periods beginning on or after October 1, 2000, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital—

(I) with respect to discharges occurring in fiscal year 2001, 75 percent of the amount otherwise applicable to the hospital under subsection (d)(5)(D)(i) of this section (referred to in this clause as the “subsection (d)(5)(D)(i) amount’’) and 25 percent of the rebased target amount (as defined in clause (i));

(II) with respect to discharges occurring in fiscal year 2002, 50 percent of the subsection (d)(5)(D)(i) amount and 50 percent of the rebased target amount;

(III) with respect to discharges occurring in fiscal year 2003, 25 percent of the subsection (d)(5)(D)(i) amount and 75 percent of the rebased target amount; and

(IV) with respect to discharges occurring after fiscal year 2003, 100 percent of the rebased target amount.

(ii) For purposes of this subparagraph, the “rebased target amount” has the meaning given the term “target amount” in subparagraph (C) except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 1996;

(II) any reference in subparagraph (C)(i) to the “first cost reporting period” described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2000; and

(III) applicable increase percentage shall only be applied under subparagraph (C)(iv) for discharges occurring in fiscal years beginning with fiscal year 2002.

(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available.

(J) For cost reporting periods beginning during fiscal year 2001, for a hospital described in subsection (d)(1)(B)(iv) of this section—

(i) the limiting or cap amount otherwise determined under subparagraph (H) shall be increased by 2 percent; and
(i) the target amount otherwise determined under subparagraph (A) shall be increased by 25 percent (subject to the limiting or cap amount determined under subparagraph (H), as increased by clause (i)).

(K)(i) With respect to discharges occurring on or after October 1, 2006, in the case of a medicare-dependent, small rural hospital, for purposes of applying subparagraph (D)—

(I) there shall be substituted for the base cost reporting period described in subparagraph (D)(i) the 12-month cost reporting period beginning during fiscal year 2002; and

(II) any reference in such subparagraph to the “first cost reporting period” described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after October 1, 2006.

(ii) This subparagraph shall only apply to a hospital if the substitution described in clause (i) results in an increase in the target amount under subparagraph (D) for the hospital.

(L)(i) For cost reporting periods beginning on or after January 1, 2009, in the case of a sole community hospital there shall be substituted for the amount otherwise determined under subsection (d)(5)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital, the subparagraph (L) rebased target amount.

(ii) For purposes of this subparagraph, the term “subparagraph (L) rebased target amount” has the meaning given the term “target amount” in subparagraph (C), except that—

(I) there shall be substituted for the base cost reporting period the 12-month cost reporting period beginning during fiscal year 2006;

(II) any reference in subparagraph (C)(i) to the “first cost reporting period” described in such subparagraph is deemed a reference to the first cost reporting period beginning on or after January 1, 2009; and

(III) the applicable percentage increase shall only be applied under subparagraph (C)(iv) for discharges occurring on or after January 1, 2009.

(4)(A)(i) The Secretary shall provide for an exception and adjustment to (and in the case of a hospital described in subsection (d)(1)(B)(ii)(III) of this section, may provide an exemption from) the method under this subsection for determining the amount of payment to a hospital where events beyond the hospital’s control or extraordinary circumstances, including changes in the case mix of such hospital, create a distortion in the increase in costs for a cost reporting period (including any distortion in the costs for the base period against which such increase is measured). The Secretary may provide for such other exemptions from, and exceptions and adjustments to, such method as the Secretary deems appropriate, including the assignment of a new base period which is more representative of the reasonable and necessary cost of inpatient services, that results in a significant distortion in the operating costs of inpatient hospital services. The Secretary shall announce a decision on any request for an exemption, exception, or adjustment under this paragraph not later than 180 days after receiving a completed application from the intermediary for such exemption, exception, or adjustment, and shall include in such decision a detailed explanation of the grounds on which such request was approved or denied.

(4)(A)(ii) The payment reductions under paragraph (3)(B)(ii)(V) shall not be considered by the Secretary in making adjustments pursuant to clause (i). In making such reductions, the Secretary shall treat the applicable update factor described in paragraph (3)(B)(vi) for a fiscal year as being equal to the market basket percentage for that year.

(B) In determining under subparagraph (A) whether to assign a new base period which is more representative of the reasonable and necessary cost to a hospital of providing inpatient services, the Secretary shall take into consideration—

(i) changes in applicable technologies and medical practices, or differences in the severity of illness among patients, that increase the hospital’s costs;

(ii) whether increases in wages and wage-related costs for hospitals located in the geographic area in which the hospital is located exceed the average of the increases in such costs paid by hospitals in the United States;

and

(iii) such other factors as the Secretary considers appropriate in determining increases in the hospital’s costs of providing inpatient services.

(C) Paragraph (1) shall not apply to payment of hospitals which is otherwise determined under paragraph (3) of section 1395f(b) of this title.

(5) In the case of any hospital having any cost reporting period of other than a 12-month period, the Secretary shall determine the 12-month period which shall be used for purposes of this section.

(6) In the case of any hospital which becomes subject to the taxes under section 3111 of the Internal Revenue Code of 1986, with respect to any or all of its employees, for part or all of a cost reporting period, and was not subject to such taxes with respect to any or all of its employees for all or part of the 12-month base cost reporting period referred to in subsection (b)(3)(A)(i) of this section, the Secretary shall provide for an adjustment by increasing the base period amount described in such subsection for such hospital by an amount equal to the amount of such taxes which would have been paid or accrued by such hospital for such base period if such hospital had been subject to such taxes for all of such base period with respect to all its employees, minus the amount of any such taxes actually paid or accrued for such base period.

(7)(A) Notwithstanding paragraph (1), in the case of a hospital or unit that is within a class of hospital described in subparagraph (B) which first receives payments under this section on or after October 1, 1997—

(i) for each of the first 2 cost reporting periods for which the hospital has a settled cost
under such subparagraph to take into account (c) Payment in accordance with State hospital average of such costs within the same class of hospital in the area of the hospital and the national average of wage-related costs State requests such treatment and if—

(1) the amount of operating costs for such respective period, or

(II) 110 percent of the national median (as estimated by the Secretary) of the target amount for hospitals in the same class as the hospital for cost reporting periods ending during fiscal year 1996, updated by the hospital market basket increase percentage to the fiscal year in which the hospital first received payments under this section, as adjusted under subparagraph (C); and

(ii) for purposes of computing the target amount for the subsequent cost reporting period, the target amount for the preceding cost reporting period is equal to the amount determined under clause (i) for such preceding period.

(B) For purposes of this paragraph, each of the following shall be treated as a separate class of hospital:

(i) Hospitals described in clause (i) of subsection (d)(1)(B) of this section and psychiatric units described in the matter following clause (v) of such subsection.

(ii) Hospitals described in clause (ii) of such subsection and rehabilitation units described in the matter following clause (v) of such subsection.

(iii) Hospitals described in clause (iv) of such subsection.

(C) In applying subparagraph (A)(i)(II) in the case of a hospital or unit, the Secretary shall provide for an appropriate adjustment to the labor-related portion of the amount determined under such subparagraph to take into account differences between average wage-related costs in the area of the hospital and the national average of such costs within the same class of hospitals.

(c) Payment in accordance with State hospital reimbursement control system; amount of payment; discontinuance of payments

(1) The Secretary may provide, in his discretion, that payment with respect to services provided by a hospital in a State may be made in accordance with a hospital reimbursement control system in a State, rather than in accordance with the other provisions of this subchapter, if the chief executive officer of the State requests such treatment and if—

(A) the Secretary determines that the system, if approved under this subsection, will apply (i) to substantially all non-Federal acute care hospitals (as defined by the Secretary) in the State and (ii) to the review of at least 75 percent of all revenues or expenses in the State for inpatient hospital services and of revenues or expenses for inpatient hospital services provided under the State's plan approved under subchapter XIX of this chapter;

(B) the Secretary has been provided satisfactory assurances as to the equitable treatment under the system of all entities (including Federal and State programs) that pay hospitals for inpatient hospital services, of hospital employees, and of hospital patients;

(C) the Secretary has been provided satisfactory assurances that under the system, over 36-month periods (the first such period beginning with the first month in which this subclause applies to that system in the State), the amount of payments made under this subchapter under such system will not exceed the amount of payments which would otherwise have been made under this subchapter not using such system;

(D) the Secretary determines that the system will not preclude an eligible organization (as defined in section 1395cc(a)(14) of this title) from negotiating directly with hospitals with respect to the organization's rate of payment for inpatient hospital services; and

(E) the Secretary determines that the system requires hospitals to meet the requirement of section 1395ccc(a)(1)(G) of this title and the system provides for the exclusion of certain costs in accordance with section 1395y(a)(14) of this title (except for such waivers thereof as the Secretary provides by regulation).

The Secretary cannot deny the application of a State under this subsection on the ground that the State's hospital reimbursement control system is based on a payment methodology other than on the basis of a diagnosis-related group or on the ground that the amount of payments made under this subchapter under such system must be less than the amount of payments which would otherwise have been made under this subchapter not using such system. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining payment amounts at no more than a specified percentage increase above the payment amounts in a base period, the State has the option of applying such test (for inpatient hospital services under part A of this subchapter) on an aggregate payment basis or on the basis of the amount of payment per inpatient discharge or admission. If the Secretary determines that the conditions described in subparagraph (C) are based on maintaining aggregate payment amounts below a national average percentage increase in total payments under part A of this subchapter for inpatient hospital services, the Secretary cannot deny the application of a State under this subsection on the ground that the State's rate of increase in such payments for such services must be less than the national average rate of increase.

(2) In determining under paragraph (1)(C) the amount of payment which would otherwise have been made under this subchapter for a State, the Secretary may provide for appropriate adjustment of such amount to take into account previous reductions effected in the amount of payments made under this subchapter in the State due to the operation of the hospital reimbursement control system in the State if the system has resulted in an aggregate rate of increase in operating costs of inpatient hospital services (as defined in subsection (d) of this section) for such hospitals in the State which is less than the aggregate rate of increase in such costs under this subchapter for hospitals in the United States.
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(3) The Secretary shall discontinue payments under a system described in paragraph (1) if the Secretary—

(A) determines that the system no longer meets the requirements of subparagraphs (A), (D), (E), and, if applicable, the requirements of paragraph (5), or

(B) has reason to believe that the assurances described in subparagraph (B) or (C) of paragraph (1) (or, if applicable, in paragraph (5)) are not being (or will not be) met.

(4) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system, and

(B) with respect to that system a waiver of certain requirements of this subchapter has been approved on or before (and which is in effect as of) April 20, 1983, pursuant to section 1395b–1(a) of this title or section 222(a) of the Social Security Amendments of 1972.

With respect to a State system described in this paragraph, the Secretary shall judge the effectiveness of such system on the basis of its rate of increase or inflation in inpatient hospital payments for individuals under this subchapter, as compared to the national rate of increase or inflation for such payments, with the State retaining the option to have the test applied on the basis of the aggregate payments under the State system as compared to aggregate payments which would have been made under the national system since October 1, 1984, to the most recent date for which annual data are available.

(5) The Secretary shall approve the request of a State under paragraph (1) with respect to a hospital reimbursement control system if—

(A) the requirements of subparagraphs (A), (B), (C), (D), and (E) of paragraph (1) have been met with respect to the system;

(B) the Secretary determines that the system—

(i) is operated directly by the State or by an entity designated pursuant to State law, (ii) provides for payment of hospitals covered under the system under a methodology (which sets forth exceptions and adjustments, as well as any method for changes in the methodology) by which rates or amounts to be paid for hospital services during a specified period are established under the system prior to the defined rate period, and

(iii) hospitals covered under the system will make such reports (in lieu of cost and other reports, identified by the Secretary, otherwise required under this subchapter) as the Secretary may require in order to properly monitor assurances provided under this subsection;

(C) the State has provided the Secretary with satisfactory assurances that operation of the system will not result in any change in hospital admission practices which result in—

(a significant reduction in the proportion of patients (receiving hospital services covered under the system) who have no third-party coverage and who are unable to pay for hospital services,

(ii) a significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is (or is likely to be) less than the anticipated charges for or costs of such services;

(iii) the refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital, or

(iv) the refusal to provide emergency services to any person who is in need of emergency services if the hospital provides such services;

(D) any change by the State in the system which has the effect of materially reducing payments to hospitals can only take effect upon 60 days notice to the Secretary and to the hospitals the payment to which is likely to be materially affected by the change; and

(E) the State has provided the Secretary with satisfactory assurances that in the development of the system the State has consulted with local governmental officials concerning the impact of the system on public hospitals.

The Secretary shall respond to requests of States under this paragraph within 60 days of the date the request is submitted to the Secretary.

(6) If the Secretary determines that the assurances described in paragraph (1)(C) have not been met with respect to any 36-month period, the Secretary may reduce payments under this subchapter to hospitals under the system in an amount equal to the amount by which the payment under this subchapter under such system for such period exceeded the amount of payments which would otherwise have been made under this subchapter not using such system.

(7) In the case of a State which made a request under paragraph (5) before December 31, 1984, for the approval of a State hospital reimbursement control system and which request was approved—

(A) in applying paragraphs (1)(C) and (6), a reference to a “36-month period” is deemed a reference to a “48-month period”, and

(B) in order to allow the State the opportunity to provide the assurances described in paragraph (1)(C) for a 48-month period, the Secretary may not discontinue payments under the system, under the authority of paragraph (3)(A) because the Secretary has reason to believe that such assurances are not being (or will not be) met, before July 1, 1986.

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographical Classification Review Board

(1)(A) Notwithstanding section 1395f(b) of this title but subject to the provisions of section 1395e of this title, the amount of the payment with respect to the operating costs of inpatient hospital services (as defined in subsection (a)(4) of this section) of a subsection (d) hospital (as defined in subparagraph (B) for inpatient hospital discharges in a cost reporting period or in a fiscal year—

(i) beginning on or after October 1, 1983, and before October 1, 1984, is equal to the sum of—
(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A) of this section, but determined without the application of subsection (a) of this section), and

(II) the DRG percentage (as defined in subparagraph (C)) of the regional adjusted DRG prospective payment rate determined under paragraph (2) for such discharges;

(ii) beginning on or after October 1, 1984, and before October 1, 1987, is equal to the sum of—

(I) the target percentage (as defined in subparagraph (C)) of the hospital's target amount for the cost reporting period (as defined in subsection (b)(3)(A) of this section, but determined without the application of subsection (a) of this section), and

(II) the DRG percentage (as defined in subparagraph (C)) of the applicable combined adjusted DRG prospective payment rate determined under subparagraph (D) for such discharges; or

(iii) beginning on or after April 1, 1988, is equal to—

(I) the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, or

(II) for discharges occurring during a fiscal year ending on or before September 30, 1996, the sum of 85 percent of the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges and 15 percent of the regional adjusted DRG prospective payment rate determined under such paragraph, but only if the average standardized amount (described in clause (i)(I) or clause (ii)(I) of paragraph (3)(D)) for hospitals within the region of, and in the same large urban or other area (or, for discharges occurring during a fiscal year ending on or before September 30, 1994, the same large urban or other area) as, the hospital is greater than the average standardized amount (described in the respective clause) for hospitals within the United States in that type of area for discharges occurring during such fiscal year.

(B) As used in this section, the term "subtraction (d) hospital" means a hospital located in one of the fifty States or the District of Columbia other than—

(i) a psychiatric hospital (as defined in section 1395x(f) of this title),

(ii) a rehabilitation hospital (as defined by the Secretary),

(iii) a hospital whose inpatients are predominantly individuals under 18 years of age,

(iv) a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or

(II) a hospital that first received payment under this subsection in 1986 which has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and that has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in fiscal year 1997, or

(v) a hospital that the Secretary has classified, at any time on or before December 31, 1990, or, in the case of a hospital that, as of December 19, 1989, is located in a State operating a demonstration project under section 1395f(b) of this title, on or before December 31, 1991 for purposes of applying exceptions and adjustments to payment amounts under this subsection, as a hospital involved extensively in treatment for or research on cancer.

(II) a hospital that was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983, that is located in a State which, as of December 19, 1989, was not operating a demonstration project under section 1395f(b) of this title, that applied and was denied, on or before December 31, 1990, for classification as a hospital involved extensively in treatment for or research on cancer under this clause (as in effect on the day before August 5, 1997), that as of August 5, 1997, is licensed for less than 50 acute care beds, and that demonstrates for the 4-year period ending on December 31, 1996, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

(III) a hospital that was recognized as a clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of February 18, 1998, that has never been reimbursed for inpatient hospital services pursuant to a reimbursement system under a demonstration project under section 1395f(b) of this title, that is a freestanding facility organized primarily for treatment of and research on cancer and is not a unit of another hospital, that as of December 21, 2000, is licensed for 162 acute care beds, and that demonstrates for the 4-year period ending on June 30, 1999, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E); and, in accordance with regulations of the Secretary, does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary). A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) shall continue to be so classified notwithstanding that it is located in the same building as, or on the same campus as, another hospital.

(C) For purposes of this subsection, for cost reporting periods beginning—

(i) on or after October 1, 1983, and before October 1, 1984, the "target percentage" is 75 percent and the "DRG percentage" is 25 percent;

(ii) on or after October 1, 1984, and before October 1, 1985, the "target percentage" is 50 percent and the "DRG percentage" is 50 percent;

(iii) on or after October 1, 1985, and before October 1, 1986, the "target percentage" is 45 percent and the "DRG percentage" is 55 percent; and

(iv) on or after October 1, 1986, and before October 1, 1987, the "target percentage" is 25 percent and the "DRG percentage" is 55 percent.

*So in original. The comma probably should not appear.
percent and the “DRG percentage” is 75 percent.

(D) For purposes of subparagraph (A)(ii)(II), the “applicable combined adjusted DRG prospective payment rate” for discharges occurring—

(i) on or after October 1, 1984, and before October 1, 1986, is a combined rate consisting of 25 percent of the national adjusted DRG prospective payment rate, and 75 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges; and

(ii) on or after October 1, 1986, and before October 1, 1987, is a combined rate consisting of 50 percent of the national adjusted DRG prospective payment rate, and 50 percent of the regional adjusted DRG prospective payment rate, determined under paragraph (3) for such discharges.

(E) For purposes of subclauses (II) and (III) of subparagraph (B)(v) only, the term “principal diagnosis code” means the condition established after study to be chiefly responsible for occasioning the admission of a patient to a hospital, except that only discharges with ICD–9–CM principal diagnosis codes of 140 through 239, V38.0, V58.1, V66.1, V66.2, or 990 will be considered to reflect such a principal diagnosis.

(2) The Secretary shall determine a national adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine a regional adjusted DRG prospective payment rate for such discharges in each region, for which payment may be made under part A of this subchapter. Each such rate shall be determined for hospitals located in urban or rural areas within the United States or within each such region, respectively, as follows:

(A) Determining Allowable Individual Hospital Costs for Base Period.—The Secretary shall determine the allowable operating costs per discharge of inpatient hospital services for the hospital for the most recent cost reporting period for which data are available.

(B) Updating for Fiscal Year 1984.—The Secretary shall update each amount determined under subparagraph (A) for fiscal year 1984 by—

(i) updating for fiscal year 1983 by the estimated average rate of change of hospital costs industry-wide between the cost reporting period used under such subparagraph and fiscal year 1983 and the most recent case-mix data available, and

(ii) projecting for fiscal year 1984 by the applicable percentage increase (as defined in subsection (b)(3)(B) of this section) for fiscal year 1984.

(C) Standardizing Amounts.—The Secretary shall standardize the amount updated under subparagraph (B) for each hospital by—

(i) excluding an estimate of indirect medical education costs (taking into account, for discharges occurring after September 30, 1986, the amendments made by section 910H(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985), except that the Secretary shall not take into account any reduction in the amount of additional payments under paragraph (5)(B)(iv) resulting from the amendment made by section 4623(a)(1) of the Balanced Budget Act of 1997 or any additional payments under such paragraph resulting from the application of section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, of section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,

(ii) adjusting for variations among hospitals by area in the average hospital wage level,

(iii) adjusting for variations in case mix among hospitals, and

(iv) for discharges occurring on or after October 1, 1986, excluding an estimate of the additional payments to certain hospitals to be made under paragraph (5)(F), except that the Secretary shall not exclude additional payments under such paragraph made as a result of the enactment of section 6003(c) of the Omnibus Budget Reconciliation Act of 1989, the enactment of section 4002(b) of the Omnibus Budget Reconciliation Act of 1990, the enactment of section 303 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or the enactment of section 402(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(D) Computing Urban and Rural Averages.—The Secretary shall compute an average of the standardized amounts determined under subparagraph (C) for the United States and for each region—

(i) for all subsection (d) hospitals located in an urban area within the United States or that region, respectively, and

(ii) for all subsection (d) hospitals located in a rural area within the United States or that region, respectively.

For purposes of this subsection, the term “region” means one of the nine census divisions, comprising the fifty States and the District of Columbia, established by the Bureau of the Census for statistical and reporting purposes; the term “urban area” means an area within a Metropolitan Statistical Area (as defined by the Office of Management and Budget) or within such similar area as the Secretary has recognized under paragraph (a) of this section by regulation; the term “large urban area” means, with respect to a fiscal year, such an urban area which the Secretary determines (in the publications described in subsection (e)(5) of this section before the fiscal year) has a population of more than 1,000,000 (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census); and the term “rural area” means any area outside such an area or similar area. A hospital located in a Metro-
adjusted DRG prospective payment rate, for each inpatient hospital discharge in a fiscal year after fiscal year 1984 involving inpatient hospital services of a subsection (d) hospital in the United States, and shall determine, for fiscal years before fiscal year 1997, a regional adjusted DRG prospective payment rate for such discharges in each region for which payment may be made under part A of this subchapter. Each such rate shall be determined for hospitals located in large urban, other urban, or rural areas within the United States and within each such region, respectively, as follows:

(A) UPDATING PREVIOUS STANDARDIZED AMOUNTS.—(i) For discharges occurring in a fiscal year beginning before October 1, 1987, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area within the United States and for hospitals located in an urban area and for hospitals located in a rural area within each region, equal to the respective average standardized amount computed for the previous fiscal year under paragraph (2)(D) or under this subparagraph, increased for the fiscal year involved by the applicable percentage increase under subsection (b)(3)(B) of this section. With respect to discharges occurring on or after October 1, 1987, the Secretary shall compute urban and rural averages on the basis of discharge weighting rather than hospital weighting, making appropriate adjustments to ensure that computation on such basis does not result in total payments under this section that are greater or less than the total payments that would have been made under this section but for this sentence, and making appropriate changes in the manner of determining the reductions under subparagraph (C)(ii).

(ii) For discharges occurring in a fiscal year beginning on or after October 1, 1987, and ending on or before September 30, 1994, the Secretary shall compute an average standardized amount for hospitals located in a large urban area, for hospitals located in a rural area, and for hospitals located in other urban areas, within the United States and within each region, equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) of this section with respect to hospitals located in the respective areas for the fiscal year involved.

(iii) For discharges occurring in the fiscal year beginning on October 1, 1994, the average standardized amount for hospitals located in a rural area shall be equal to the average standardized amount for hospitals located in an urban area. For discharges occurring on or after October 1, 1994, the Secretary shall adjust the ratio of the labor portion to non-labor portion of each average standardized amount to equal such ratio for the national average of all standardized amounts.

(iv) Subject to subclause (II), for discharges occurring in a fiscal year beginning on or after October 1, 1995, the Secretary shall compute an average standardized amount for hospitals located in a large urban area and for hospitals located in other areas within the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in an urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(ii) for hospitals located in a rural area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (D), reduced under subparagraph (E), and adjusted under subparagraph (F)) for hospitals located in a rural area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(H) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—The Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals’ costs which are attributable to wages and wage-related costs, of the national and regional DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level.

(3) The Secretary shall determine a national adjusted DRG prospective payment rate, for
United States and within each region equal to the respective average standardized amount computed for the previous fiscal year under this subparagraph increased by the applicable percentage increase under subsection (b)(3)(B)(i) of this section with respect to hospitals located in the respective areas for the fiscal year involved.

(II) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute a standardized amount for hospitals located in any area within the United States and within each region equal to the standardized amount computed for the previous fiscal year under this subparagraph for hospitals located in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B)(i) of this section for the fiscal year involved.

(v) Average standardized amounts computed under this paragraph shall be adjusted to reflect the most recent case-mix data available.

(vi) Insofar as the Secretary determines that the adjustments under paragraph (4)(C)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of discharges that do not reflect real changes in case-mix, the Secretary may adjust the average standardized amounts computed under this paragraph for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(B) REDUCING FOR VALUE OF OUTLIER PAYMENTS.—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (A) by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on DRG prospective payment amounts which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(C) MAINTAINING BUDGET NEUTRALITY FOR FISCAL YEAR 1995.—(i) For discharges occurring in fiscal year 1995, the Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) of this section for that fiscal year.

(ii) For discharges occurring after September 30, 1996, the Secretary shall further reduce each of the average standardized amounts (in a proportion which takes into account the differing effects of the standardization effected under paragraph (2)(C)(i)) so as to provide for a reduction in the total of the payments attributable to this paragraph made for discharges occurring on or after October 1, 1996, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) that would have resulted from the enactment of the amendments made by section 1804 of the Medicare and Medicaid Budget Reconciliation Amendments of 1995 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (i)(II) of paragraph (5)(B) (determined without regard to amendments made by the Omnibus Budget Reconciliation Act of 1990) were applied for discharges occurring on or after such date instead of the factor described in clause (ii) of that paragraph.

(D) COMPUTING DRG-SPECIFIC RATES FOR HOSPITALS.—For each discharge classified within a diagnosis-related group, the Secretary shall establish for the fiscal year a national DRG prospective payment rate and shall establish, for fiscal years before fiscal year 1997, a regional DRG prospective payment rate for each region which is equal—

(i) for fiscal years before fiscal year 2004, for hospitals located in a large urban area in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in such a large urban area in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group;

(ii) for fiscal years before fiscal year 2004, for hospitals located in other areas in the United States or that region (respectively), to the product of—

(I) the average standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year for hospitals located in other areas in the United States or that region, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group; and

(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of—

(I) the applicable standardized amount (computed under subparagraph (A), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C)) for the fiscal year; and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(E) ADJUSTING FOR DIFFERENT AREA WAGE LEVELS.—

(i) IN GENERAL.—Except as provided in clause (ii) or (iii), the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates computed under subparagraph (D) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Not later than October 1, 1990, and October 1, 1993 (and at least every 12 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of a survey conducted by the Secretary (and
updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. Not less often than once every 3 years the Secretary (through such survey or otherwise) shall measure the earnings and paid hours of employment by occupational category and shall exclude data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility services. Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment. The Secretary shall apply the previous sentence for any period as if the amendments made by section 10324(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the amendments made by section 403(a)(1) of the Patient Protection and Affordable Care Act had not been enacted.

(ii) ALTERNATIVE PROPORTION TO BE ADJUSTED BEGINNING IN FISCAL YEAR 2005.—For discharges occurring on or after October 1, 2004, the Secretary shall substitute “62 percent” for the proportion described in the first sentence of clause (i), unless the application of this clause would result in lower payments to a hospital than would otherwise be made.

(iii) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN FRONTIER STATES.—

(I) In general.—Subject to subparagraph (IV), for discharges occurring on or after October 1, 2010, the area wage index applicable under this subparagraph to any hospital which is located in a frontier State (as defined in subclause (II)) may not be less than 1.00.

(II) FRONTIER STATE DEFINED.—In this clause, the term “frontier State” means a State in which at least 50 percent of the counties in the State are frontier counties.

(III) FRONTIER COUNTY DEFINED.—In this clause, the term “frontier county” means a county in which the population per square mile is less than 6.

(IV) LIMITATION.—This clause shall not apply to any hospital located in a State that receives a non-labor related share adjustment under paragraph (5)(H).

(4)(A) The Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups.

(B) For each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(C)(i) The Secretary shall adjust the classifications and weighting factors established under subparagraphs (A) and (B), for discharges in fiscal year 1988 and at least annually thereafter, to reflect changes in treatment patterns, technology (including a new medical service or technology under paragraph (5)(K)), and other factors which may change the relative use of hospital resources.

(ii) For discharges in fiscal year 1990, the Secretary shall reduce the weighting factor for each diagnosis-related group by 1.22 percent.

(iii) Any such adjustment under clause (i) for discharges in a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment.

(D)(i) For discharges occurring on or after October 1, 2008, the diagnosis-related group to be assigned under this paragraph for a discharge described in clause (ii) shall be a diagnosis-related group that does not result in higher payment based on the presence of a secondary diagnosis code described in clause (iv).

(ii) A discharge described in this clause is a discharge which meets the following requirements:

(I) The discharge includes a condition identified by a diagnosis code selected under clause (iv) as a secondary diagnosis.

(II) But for clause (i), the discharge would have been classified to a diagnosis-related group that results in a higher payment based on the presence of a secondary diagnosis code selected under clause (iv).

(III) At the time of admission, no code selected under clause (iv) was present.

(iii) As part of the information required to be reported by a hospital with respect to a discharge of an individual in order for payment to be made under this subsection, for discharges occurring on or after October 1, 2007, the information shall include the secondary diagnosis of the individual at admission.

(iv) By not later than October 1, 2007, the Secretary shall select diagnosis codes associated with at least two conditions, each of which codes meets all of the following requirements (as determined by the Secretary):

(I) Cases described by such code have a high cost or high volume, or both, under this subchapter.

(II) The code results in the assignment of a case to a diagnosis-related group that has a higher payment when the code is present as a secondary diagnosis.

(III) The code describes such conditions that could reasonably have been prevented through the application of evidence-based guidelines.

The Secretary may from time to time revise (through addition or deletion of codes) the diagnosis codes selected under this clause so long as there are diagnosis codes associated with at least two conditions selected for discharges occurring during any fiscal year.

(v) In selecting and revising diagnosis codes under clause (iv), the Secretary shall consult with the Centers for Disease Control and Prevention and other appropriate entities.

(vi) Any change resulting from the application of this subparagraph shall not be taken into account in adjusting the weighting factors under
subparagraph (C)(i) or in applying budget neutrality under subparagraph (C)(iii).

(5)(A)(i) For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary shall provide for an additional payment for a subsection (d) hospital for any discharge in a diagnosis-related group, the length of stay of which exceeds the mean length of stay for discharges within that group by a fixed number of days, or exceeds such mean length of stay by some fixed number of standard deviations, whichever is the fewer number of days.

(ii) For cases which are not included in clause (i), a subsection (d) hospital may request additional payments in any case where charges, adjusted to costs, exceed a fixed multiple of the applicable DRG prospective payment rate, or exceed such other fixed dollar amount, whichever is greater, or, for discharges in fiscal years beginning on or after October 1, 1994, exceed the sum of the applicable DRG prospective payment rate plus any amounts payable under subparagaphs (B) and (F) plus a fixed dollar amount determined by the Secretary.

(iii) The amount of such additional payment under clauses (i) and (ii) shall be determined by the Secretary and shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v)) approximate the marginal cost of care beyond the cutoff point applicable under clause (i) or (ii).

(iv) The total amount of the additional payments made under this subparagraph for discharges in a fiscal year may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year.

(v) The Secretary shall provide that—

(I) the day outlier percentage for fiscal year 1995 shall be 75 percent of the day outlier percentage for fiscal year 1994;

(II) the day outlier percentage for fiscal year 1996 shall be 50 percent of the day outlier percentage for fiscal year 1994; and

(III) the day outlier percentage for fiscal year 1997 shall be 25 percent of the day outlier percentage for fiscal year 1994.

(vi) For purposes of this subparagraph, the term "day outlier percentage" means, for a fiscal year, the percentage of the total additional payments made by the Secretary under this subparagraph for discharges in that fiscal year which are additional payments under clause (i).

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2) of this section, except as follows:

(i) The amount of such additional payment shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(i)(II) or, if applicable, the amount determined under paragraph (1)(A)(iii) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A), by (II) the indirect teaching adjustment factor described in clause (ii).

(ii) For purposes of clause (i)(II), the indirect teaching adjustment factor is equal to $c \times (((1+r) to the nth power) - 1)$, where "r" is the ratio of the hospital's full-time equivalent interns and residents to beds and "n" equals 405. Subject to clause (ix), for discharges occurring—

(I) on or after October 1, 1988, and before October 1, 1997, "c" is equal to 1.89;

(II) during fiscal year 1998, "c" is equal to 1.72;

(III) during fiscal year 1999, "c" is equal to 1.6;

(IV) during fiscal year 2000, "c" is equal to 1.47;

(V) during fiscal year 2001, "c" is equal to 1.54;

(VI) during fiscal year 2002, "c" is equal to 1.6;

(VII) on or after October 1, 2002, and before April 1, 2004, "c" is equal to 1.35;

(VIII) on or after April 1, 2004, and before October 1, 2004, "c" is equal to 1.42;

(IX) during fiscal year 2005, "c" is equal to 1.42;

(X) during fiscal year 2006, "c" is equal to 1.37;

(XI) during fiscal year 2007, "c" is equal to 1.32; and

(XII) on or after October 1, 2007, "c" is equal to 1.35.

(iii) In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.

(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2010, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalence if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(II) Effective for discharges occurring on or after July 1, 2010, all the time spent by an intern or resident in patient care activities in a nonprovider setting shall be counted towards the determination of full-time equivalence if a hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with re-
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spect to the hospital’s most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(P)(i) of this section shall apply for purposes of this clause. The provisions of subsections (h)(4)(H)(vii), (h)(8), and (h)(8) of this section shall apply with respect to the first sentence of this clause in the same manner as they apply with respect to subsection (h)(4)(P)(i) of this section.

(vi) For purposes of clause (ii)—
(I) “r” may not exceed the ratio of the number of interns and residents, subject to the limit under clause (v), with respect to the hospital for its most recent cost reporting period to the hospital’s available beds (as defined by the Secretary) during that cost reporting period, and
(II) for the hospital’s cost reporting periods beginning on or after October 1, 1997, subject to the limits described in clauses (iv) and (v), the total number of full-time equivalent residents for payment purposes shall equal the average of the actual full-time equivalent resident count pursuant to subclause (II) of clause (vi) is based on the equivalent of full twelve-month cost reporting periods.

In the case of the first cost reporting period beginning on or after October 1, 1997, subclause (II) shall be applied by using the average for such period and the preceding cost reporting period.

(vii) If any cost reporting period beginning on or after October 1, 1997, is not equal to twelve months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent residency count pursuant to subclause (II) of clause (vi) is based on the equivalent of full twelve-month cost reporting periods.

(viii) Rules similar to the rules of subsection (h)(4)(H) of this section shall apply for purposes of clauses (v) and (vi).

(ix) For discharges occurring on or after July 1, 2005, insofar as an additional payment amount under this subparagraph is attributable to resident positions redistributed to a hospital under subsection (h)(7)(B) of this section, in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in a manner as if “c” were equal to 0.66 with respect to such resident positions.

(x) For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(\textsuperscript{x}) The provisions of subparagraph (K) of subsection (b)(4) shall apply under this subparagraph in the same manner as they apply under such subparagraph.

(II) In determining the hospital’s number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—
(aa) is recognized as a subsection (d) hospital;
(bb) is recognized as a subsection (d) Puerto Rico hospital;
(cc) is reimbursed under a reimbursement system authorized under section 1395f(b)(3) of this title; or
(dd) is a provider-based hospital outpatient department.

(III) In determining the hospital’s number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.

(C)(i) The Secretary shall provide for such exceptions and adjustments to the payment amounts established under this subsection (other than under paragraph (9)) as the Secretary deems appropriate to take into account the special needs of regional and national referral centers (including those hospitals of 275 or more beds located in rural areas). A hospital which is classified as a rural hospital may appeal to the Secretary to be classified as a rural referral center under this clause on the basis of criteria (established by the Secretary) which shall allow the hospital to demonstrate that it should be so reclassified by reason of certain of its operating characteristics being similar to those of a typical urban hospital located in the same census region and which shall not require a rural osteopathic hospital to have more than 3,000 discharges in a year in order to be classified as a rural referral center. Such characteristics may include wages, scope of services, service area, and the mix of medical specialties. The Secretary shall publish the criteria not later than August 17, 1984, for implementation by October 1, 1984. An appeal allowed under this clause must be submitted to the Secretary (in such form and manner as the Secretary may prescribe) during the quarter before the first quarter of the hospital’s cost reporting period (or, in the case of a cost reporting period beginning during October 1984, during the first quarter of that period), and the Secretary must make a final determination with respect to such appeal within 60 days after the date the appeal was submitted. Any payment adjustments necessitated by a reclassification based upon the appeal shall be effective at the beginning of such cost reporting period.

(ii) The Secretary shall provide, under clause (i), for the classification of a rural hospital as a regional referral center if the hospital has a case mix index equal to or greater than the median case mix index for hospitals (other than hos-
hospitals with approved teaching programs) located in an urban area in the same region (as defined in paragraph (2)(D)), has at least 5,000 discharges a year or, if less, the median number of discharges in urban hospitals in the region in which the hospital is located (or, in the case of a rural osteopathic hospital, meets the criterion established by the Secretary under clause (i) with respect to the annual number of discharges for such hospitals), and meets any other criteria established by the Secretary under clause (i).

(D)(i) For any cost reporting period beginning on or after April 1, 1990, with respect to a subsection (d) hospital which is a sole community hospital, payment under paragraph (1)(A) shall be—

(I) an amount based on 100 percent of the hospital’s target amount for the cost reporting period, as defined in subsection (b)(3)(C) of this section, or

(II) the amount determined under paragraph (1)(A)(iii), whichever results in greater payment to the hospital.

(ii) In the case of a sole community hospital that experiences, in a cost reporting period compared to the previous cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing inpatient hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iii) For purposes of this subchapter, the term “sole community hospital” means any hospital—

(I) that the Secretary determines is located more than 35 road miles from another hospital,

(II) that, by reason of factors such as the time required for an individual to travel to the nearest alternative source of appropriate inpatient care (in accordance with standards promulgated by the Secretary), location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to individuals in a geographic area who are entitled to benefits under part A of this subchapter, or

(III) that is located in a rural area and designated by the Secretary as an essential access community hospital under section 1395i–4(i)(1) of this title as in effect on September 30, 1997.

(iv) The Secretary shall promulgate a standard for determining whether a hospital meets the criteria for classification as a sole community hospital under clause (iii)(II) because of the time required for an individual to travel to the nearest alternative source of appropriate inpatient care.

(v) If the Secretary determines that, in the case of a hospital located in a rural area and designated by the Secretary as an essential access community hospital under section 1395i–4(i)(1) of this title as in effect on September 30, 1997, the hospital has incurred increases in reasonable costs during a cost reporting period as a result of becoming a member of a rural health network (as defined in section 1395i–4(d) of this title), in the case in which it is located, and in incurring such increases, the hospital will increase its costs for subsequent cost reporting periods, the Secretary shall increase the hospital’s target amount under subsection (b)(3)(C) of this section to account for such incurred increases.

(E)(i) The Secretary shall estimate the amount of reimbursement made for services described in section 1395y(a)(14) of this title with respect to which payment was made under part B of this subchapter in the base reporting periods referred to in paragraph (2)(A) and with respect to which payment is no longer being made.

(ii) The Secretary shall provide for an adjustment to the payment for subsection (d) hospitals in each fiscal year so as appropriately to reflect the net amount described in clause (i).

(F)(i) Subject to subsection (v), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX of this chapter), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

(ii) Subject to clause (ix), the amount of such payment for each discharge shall be determined by multiplying (I) the sum of the amount determined under paragraph (1)(A)(ii)(II) (or, if applicable, the amount determined under paragraph (1)(A)(iii)) and, for cases qualifying for additional payment under subparagraph (A)(i), the amount paid to the hospital under subparagraph (A) for that discharge, by (II) the disproportionate share adjustment percentage established under clause (iii) or (iv) for the cost reporting period in which the discharge occurs.

(iii) The disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (i)(II) is equal to 35 percent.

(iv) The disproportionate share adjustment percentage for a cost reporting period for a hospital that is not described in clause (i)(II) and that—

(I) is located in an urban area and has 100 or more beds or is described in the second sentence of clause (v), is equal to the percentage determined in accordance with the applicable formula described in clause (vii);

(II) is located in an urban area and has less than 100 beds, is equal to 5 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percentage determined in accordance with clause (xiii);
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(III) is located in a rural area and is not described in subclause (IV) or (V) or in the second sentence of clause (v), is equal to 4 percent or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii);

(IV) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is classified as a sole community hospital under subparagraph (D), is equal to 10 percent or, if greater, the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, the greater of the percentages determined under clause (x) or (xi);

(V) is located in a rural area, is classified as a rural referral center under subparagraph (C), and is not classified as a sole community hospital under subparagraph (D), is equal to the percent determined in accordance with the applicable formula described in clause (viii) or, subject to clause (xiv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (x);

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after January 1, 1991), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients", for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital’s patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital’s patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital’s patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX of this chapter, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital’s patient days for such period.

In determining under subclause (II) the number of the hospital’s patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX of this chapter, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

(vii) The formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(I) is—

(I) in the case of such a hospital with a disproportionate patient percentage (as defined in clause (vi)) greater than 20—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, \(P \cdot 20.2)(.65) + 5.62\),

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, \(P \cdot 20.2)(.7) + 5.62\),

(c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, \(P \cdot 20.2)(.8) + 5.88\), and

(d) for discharges occurring on or after October 1, 1994, \(P \cdot 20.2)(.825) + 5.88\); or

(II) in the case of any other such hospital—

(a) for discharges occurring on or after April 1, 1990, and on or before December 31, 1990, \(P \cdot 15)(.6) + 2.5\),

(b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, \(P \cdot 15)(.6) + 2.5\),

(c) for discharges occurring on or after October 1, 1993, \(P \cdot 15)(.65) + 2.5\),

where \(P\) is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(viii) Subject to clause (xiv), the formula used to determine the disproportionate share adjustment percentage for a cost reporting period for a hospital described in clause (iv)(IV) or (iv)(V) is the percentage determined in accordance with the following formula: \(P \cdot 30)(.6) + 4.0\), where

\(\text{So in original. Probably should be followed by "and".}\)
“P” is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(i) In the case of discharges occurring—

(I) during fiscal year 1998, the additional payment amount otherwise determined under clause (ii) shall be reduced by 1 percent;

(II) during fiscal year 1999, such additional payment amount shall be reduced by 2 percent;

(III) during fiscal years 2000 and 2001, such additional payment amount shall be reduced by 3 percent and 2 percent, respectively;

(IV) during fiscal year 2002, such additional payment amount shall be reduced by 3 percent; and

(V) during fiscal year 2003 and each subsequent fiscal year, such additional payment amount shall be reduced by 0 percent.

(x) Subject to clause (xiv), for purposes of clause (iv)(VI) (relating to sole community hospitals), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula:

\[ P \times (1.65) + 2.5 \]

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where “P” is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula:

\[ P \times (1.65) + 2.5 \]

(II) is equal to or exceeds 19.3, but is less than 30.0, such adjustment percentage is equal to 5.25 percent; or

(III) is equal to or exceeds 30, such adjustment percentage is equal to 10 percent,

where “P” is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(xii) Subject to clause (xiv), for purposes of clause (iv)(III) (relating to small rural hospitals generally), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula:

\[ P \times (1.65) + 2.5 \]

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where “P” is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(xiii) Subject to clause (xiv), for purposes of clause (iv)(II) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) that—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula:

\[ P \times (1.65) + 2.5 \]

(II) is equal to or exceeds 19.3, such adjustment percentage is equal to 5.25 percent,

where “P” is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(xiv) In the case of discharges occurring on or after April 1, 2004, for purposes of clause (ix), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vi) (relating to large, urban hospitals).

(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 12 percent for a hospital that is not classified as a rural referral center under subparagraph (C) or is—

(G) a hospital that experiences, in a cost reporting period, a decrease of more than 5 percent in its total number of inpatient cases due to circumstances beyond its control, the Secretary shall provide for such adjustment to the payment amounts under this subsection (other than under paragraph (9)) as may be necessary to fully compensate the hospital for the fixed costs it incurs in the period in providing hospital services, including the reasonable cost of maintaining necessary core staff and services.

(iv) The term “medicare-dependent, small rural hospital” means, with respect to any cost
reporting period to which clause (i) applies, any hospital—

(I) located in a rural area,

(II) that has not more than 100 beds,

(III) that is not classified as a sole community hospital under subparagraph (D), and

(IV) for which not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in fiscal year 1987, or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report, were attributable to inpatients entitled to benefits under part A of this subchapter.

(H) The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii.

(I)(i) The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate.

(ii) in making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year.

(J)(i) The Secretary shall treat the term ‘transfer case’ (as defined in subparagraph (I)(ii)) as including the case of a qualified discharge (as defined in clause (ii)), which is classified within a diagnosis-related group described in clause (iii), and which occurs on or after October 1, 1998. In the case of a qualified discharge for which a substantial portion of the costs of care are incurred in the early days of the inpatient stay (as defined by the Secretary), in no case may the payment amount otherwise provided under this subsection exceed an amount equal to the sum of—

(I) 50 percent of the amount of payment under this subsection for transfer cases (as established under subparagraph (I)(i)), and

(II) 50 percent of the amount of payment which would have been made under this subsection with respect to the qualified discharge if no transfer were involved.

(ii) For purposes of clause (i), subject to clause (iv), the term ‘qualified discharge’ means a discharge classified with a diagnosis-related group (described in clause (iii)) of an individual from a subsection (d) hospital, if upon such discharge the individual—

(I) is admitted as an inpatient to a hospital or hospital unit that is not a subsection (d) hospital for the provision of inpatient hospital services;

(II) is admitted to a skilled nursing facility;

(III) is provided home health services from a home health agency, if such services relate to the condition or diagnosis for which such individual received inpatient hospital services from the subsection (d) hospital, and if such services are provided within an appropriate period (as determined by the Secretary); or

(IV) for discharges occurring on or after October 1, 2000, the individual receives post discharge services described in clause (iv)(I).

(iii) Subject to clause (iv), a diagnosis-related group described in this clause is—

(I) 1 of 10 diagnosis-related groups selected by the Secretary based upon a high volume of discharges classified within such groups and a disproportionate use of post discharge services described in clause (ii); and

(II) a diagnosis-related group specified by the Secretary under clause (iv)(II).

(iv) The Secretary shall include in the proposed rule published under subsection (e)(5)(A) of this section for fiscal year 2001, a description of the effect of this subparagraph. The Secretary may include in the proposed rule (and in the final rule published under paragraph (6)) for fiscal year 2001 or a subsequent fiscal year, a description of—

(I) post-discharge services not described in subclauses (I), (II), and (III) of clause (ii), the receipt of which results in a qualified discharge; and

(II) diagnosis-related groups described in clause (iii)(I) in addition to the 10 selected under such clause.

(K)(i) Effective for discharges beginning on or after October 1, 2001, the Secretary shall establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under this subsection. Such mechanism shall be established after notice and opportunity for public comment (in the publications required by subsection (e)(5) of this section for a fiscal year or otherwise). Such mechanism shall be modified to meet the requirements of clause (viii).

(ii) The mechanism established pursuant to clause (i) shall—

(I) apply to a new medical service or technology if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate (applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved);

(II) provide for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than two years and not more than three years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology;

(III) provide for additional payment to be made under this subsection with respect to discharges involving a new medical service or technology described in subclause (I) that occur during the period described in subclause (II) in an amount that adequately reflects the estimated average cost of such service or technology; and

(IV) provide that discharges involving such a service or technology that occur after the close of the period described in subclause (II)
will be classified within a new or existing diagnosis-related group with a weighting factor under paragraph (4)(B) that is derived from cost data collected with respect to discharges occurring during such period.

(iii) For purposes of clause (ii)(II), the term "inpatient hospital code" means any code that is used with respect to inpatient hospital services for which payment may be made under this subsection and includes a alphanumeric code issued under the International Classification of Diseases, 9th Revision, Clinical Modification ("ICD–9–CM") and its subsequent revisions.

(iv) For purposes of clause (ii)(III), the term "additional payment" means, with respect to a discharge for a new medical service or technology described in clause (ii)(I), an amount that exceeds the prospective payment rate otherwise applicable under this subsection to discharges involving such service or technology that would be made but for this subparagraph.

(v) The requirement under clause (ii)(III) for an additional payment may be satisfied by means of a new-technology group (described in subparagraph (L)), an add-on payment, a payment adjustment, or any other similar mechanism for increasing the amount otherwise payable with respect to a discharge under this subsection. The Secretary may not establish a separate fee schedule for such additional payment for such services and technologies, by utilizing a methodology established under subsection (a) or (h) of section 1395m of this title to determine the amount of such additional payment, or by other similar mechanisms or methodologies.

(vi) For purposes of this subparagraph and subparagraph (L), a medical service or technology will be considered a "new medical service or technology" if the service or technology meets criteria established by the Secretary after notice and an opportunity for public comment.

(vii) Under the mechanism under this subparagraph, the Secretary shall provide for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date.

(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of individuals entitled to benefits under part A of this subchapter as follows:

  (I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under this subparagraph is pending.

  (II) The Secretary shall accept comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement.

(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Secretary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).

(L)(i) In establishing the mechanism under subparagraph (K), the Secretary may establish new-technology groups into which a new medical service or technology will be classified if, based on the estimated average costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate.

(ii) Such groups—

  (I) shall not be based on the costs associated with a specific new medical service or technology, but

  (II) shall, in combination with the applicable standardized amounts and the weighting factors assigned to such groups under paragraph (4)(B), reflect such cost cohorts as the Secretary determines are appropriate for all new medical services and technologies that are likely to be provided as inpatient hospital services in a fiscal year.

(iii) The methodology for classifying specific hospital discharges within a diagnosis-related group under paragraph (4)(A) or a new-technology group shall provide that a specific hospital discharge may not be classified within both a diagnosis-related group and a new-technology group.

(6) The Secretary shall provide for publication in the Federal Register, on or before the August 1 before each fiscal year (beginning with fiscal year 1984), of a description of the methodology and data used in computing the adjusted DRG prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B) of this section.

(7) There shall be no administrative or judicial review under section 1395oo of this title or otherwise of—

  (A) the determination of the requirement, or the proportional amount, of any adjustment effectuated pursuant to subsection (e)(1) of this section or the determination of the applicable percentage increase under paragraph (12)(A)(ii).

  (B) the establishment of diagnosis-related groups, of the methodology for the classification of discharges within such groups, and of the appropriate weighting factors thereof under paragraph (4), including the selection...
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(8)(A) In the case of any hospital which is located in an area which is, at any time after April 20, 1983, reclassified from an urban to a rural area, payments to such hospital for the first two cost reporting periods for which such reclassification is effective shall be made as follows:

(i) For the first such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to two-thirds of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(ii) For the second such cost reporting period, payment shall be equal to the amount payable to such hospital for such reporting period on the basis of the rural classification, plus an amount equal to one-third of the amount (if any) by which—

(I) the amount which would have been payable to such hospital for such reporting period on the basis of an urban classification, exceeds

(II) the amount payable to such hospital for such reporting period on the basis of the rural classification.

(B)(i) For purposes of this subsection, the Secretary shall treat a hospital located in a rural county adjacent to one or more urban areas as being located in the urban metropolitan statistical area to which the greatest number of workers in the county commute, if the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) described in clause (ii), if the commuting rates used in determining outlying counties (or, for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas).

(ii) The standards described in this clause for cost reporting periods beginning in a fiscal year—

(I) before fiscal year 2003, are the standards published in the Federal Register on January 3, 1980, or, at the election of the hospital with respect to fiscal years 2001 and 2002, standards so published on March 30, 1990; and

(II) after fiscal year 2002, are the standards published in the Federal Register by the Director of the Office of Management and Budget based on the most recent available decennial population data.

Subparagraphs (C) and (D) shall not apply with respect to the application of subclause (I).

(C)(i) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as being located in an urban area, or by treating hospitals located in one urban area as being located in another urban area—

(I) reduces the wage index for that urban area (as applied under this subsection) by 1 percentage point or less, the Secretary, in calculating such wage index under this subsection, shall exclude those hospitals so treated, or

(II) reduces the wage index for that urban area by more than 1 percentage point (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if such hospitals were located in such urban area).

(ii) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if such hospitals were located in such urban area).

(iii) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) may not result in the reduction of any county’s wage index to a level below the wage index for rural areas in the State in which the county is located.

(iv) The application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or of the Secretary under paragraph (10) may not result in a reduction in an urban area’s wage index if—

(I) the urban area has a wage index below the wage index for rural areas in the State in which it is located; or

(II) the urban area is located in a State that is composed of a single urban area.

(v) This subparagraph shall apply with respect to discharges occurring in a fiscal year only if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) for the fiscal year that is based on the use of Metropolitan Statistical Area classifications.

(D) The Secretary shall make a proportional adjustment in the standardized amounts determined under paragraph (3) to assure that the provisions of subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) do not result in aggregate payments under this section that are greater or less than those that would otherwise be made.
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For purposes of this subsection, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital described in clause (ii), the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located.

(ii) For purposes of clause (i), a subsection (d) hospital described in this clause is a subsection (d) hospital that is located in an urban area (as defined in paragraph (2)(D)) and satisfies any of the following criteria:

(I) The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the Federal Register on February 27, 1992 (57 Fed. Reg. 6725)).

(II) The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).

(III) The hospital would qualify as a rural, regional, or national referral center under paragraph (5)(C) or as a sole community hospital located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

(A) Notwithstanding section 1395f(b) of this title but subject to the provisions of section 1395e of this title, the amount of the payment with respect to the operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges is equal to the sum of—

(i) the applicable Puerto Rico percentage (specified in subparagraph (E)) of the Puerto Rico adjusted DRG prospective payment rate (determined under subparagraph (B) or (C)) for such discharges,

(ii) the applicable Federal percentage (specified in subparagraph (E)) of—

(I) for discharges beginning in a fiscal year beginning on or after October 1, 1997, and before October 1, 2003, the discharge-weighted average of—

(aa) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area,

(bb) such rate for hospitals located in other urban areas, and

(cc) such rate for hospitals located in a rural area,

for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels; and

(II) for discharges in a fiscal year beginning on or after October 1, 2003, the national DRG prospective payment rate determined under paragraph (3)(D)(iii) for hospitals located in any area for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels.

As used in this section, the term “subsection (d) Puerto Rico hospital” means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the 50 States.

(B) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate, for each inpatient hospital discharge in fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this chapter. Such rate shall be determined for such hospitals located in urban or rural areas within Puerto Rico, as follows:

(i) The Secretary shall determine the target amount (as defined in subsection (b)(3)(A) of this section) for the hospital for the cost reporting period beginning in fiscal year 1987 and increase such amount by prorating the applicable percentage increase (as defined in subsection (b)(3)(B) of this section) to update the amount to the midpoint in fiscal year 1988.

(ii) The Secretary shall standardize the amount determined under clause (i) for each hospital by—

(I) excluding an estimate of indirect medical education costs,

(II) adjusting for variations among hospitals by area in the average hospital wage level,

(III) adjusting for variations in case mix among hospitals, and

(IV) excluding an estimate of the additional payments to certain subsection (d) Puerto Rico hospitals to be made under subparagraph (D)(iii) (relating to disproportionate share payments).

(iii) The Secretary shall compute a discharge weighted average of the standardized amounts determined under clause (ii) for all hospitals located in an urban area and for all hospitals located in a rural area (as such terms are defined in paragraph (2)(D)).

(iv) The Secretary shall reduce the average standardized amount by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(iii) (relating to disproportionate share payments).

(v) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (iii) and reduced under clause (iv)) for hospitals located in an urban or rural area, respectively, and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(vi) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals’ costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (v) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rican average hospital wage level.

(C) The Secretary shall determine a Puerto Rico adjusted DRG prospective payment rate,
for each inpatient hospital discharge after fiscal year 1988 involving inpatient hospital services of a subsection (d) Puerto Rico hospital for which payment may be made under part A of this subchapter. Such rate shall be determined for hospitals located in urban or rural areas within Puerto Rico as follows:

(i)(I) For discharges in a fiscal year after fiscal year 1988 and before fiscal year 2004, the Secretary shall compute an average standardized amount for hospitals located in an urban area and for hospitals located in a rural area equal to the respective average standardized amount computed for the previous fiscal year under subparagraph (B)(iii) or under this clause, increased for fiscal year 1989 by the applicable percentage increase under subsection (b)(3)(B) of this section, and adjusted for subsequent fiscal years in accordance with the final determination of the Secretary under subsection (e)(4) of this section, and adjusted to reflect the most recent case-mix data available.

(ii) For discharges occurring in a fiscal year (beginning with fiscal year 2004), the Secretary shall compute an average standardized amount for hospitals located in any area of Puerto Rico that is equal to the average standardized amount computed under subclause (I) for fiscal year 2003 for hospitals in a large urban area (or, beginning with fiscal year 2005, for all hospitals in the previous fiscal year) increased by the applicable percentage increase under subsection (b)(3)(B) of this section for the fiscal year involved.

(iii) The Secretary shall reduce each of the average standardized amounts (or for fiscal year 2004 and thereafter, the average standardized amount) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this paragraph which are additional payments described in subparagraph (D)(i) (relating to outlier payments).

(iv) For each discharge classified within a diagnosis-related group for hospitals located in an urban or rural area, respectively, the Secretary shall establish a Puerto Rico DRG prospective payment rate equal to the product of—

(I) the average standardized amount (computed under clause (i) and reduced under clause (ii)), and

(II) the weighting factor (determined under paragraph (4)(B)) for that diagnosis-related group.

(iv)(I) The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the Puerto Rico DRG prospective payment rate computed under clause (iii) for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the Puerto Rico average hospital wage level. The second and third sentences of paragraph (3)(E)(i) shall apply to subsection (d) Puerto Rico hospitals under this clause in the same manner as they apply to subsection (d) hospitals under such paragraph and, for purposes of this clause, any reference in such paragraph to a subsection (d) hospital is deemed a reference to a subsection (d) Puerto Rico hospital.

(ii) For discharges occurring on or after October 1, 2004, the Secretary shall substitute “62 percent” for the proportion described in the first sentence of clause (i), unless the application of this subclause would result in lower payments to a hospital than would otherwise be made.

(D) The following provisions of paragraph (5) shall apply to subsection (d) Puerto Rico hospitals receiving payment under this paragraph in the same manner and to the extent as they apply to subsection (d) hospitals receiving payment under this subsection:

(i) Subparagraph (A) (relating to outlier payments).

(ii) Subparagraph (B) (relating to payments for indirect medical education costs), except that for this purpose the sum of the amount determined under subparagraph (A) of this paragraph and the amount paid to the hospital under clause (i) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(B)(i)(D).

(iii) Subparagraph (F) (relating to disproportionate share payments), except that for this purpose the sum described in clause (ii) of this subparagraph shall be substituted for the sum referred to in paragraph (5)(F)(xii)(I).

(iv) Subparagraph (H) (relating to exceptions and adjustments).

(E) For purposes of subparagraph (A), for discharges occurring—

(i) on or after October 1, 1987, and before October 1, 1997, the applicable Puerto Rico percentage is 75 percent and the applicable Federal percentage is 25 percent;

(ii) on or after October 1, 1997, and before April 1, 2004, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

(iii) on or after April 1, 2004, and before October 1, 2004, the applicable Puerto Rico percentage is 37.5 percent and the applicable Federal percentage is 62.5 percent; and

(iv) on or after October 1, 2004, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent.

(10)(A) There is hereby established the Medicare Geographic Classification Review Board (hereinafter in this paragraph referred to as the “Board”).

(B)(i) The Board shall be composed of 5 members appointed by the Secretary without regard to the provisions of title 5, governing appointments in the competitive service. Two of such members shall be representative of subsection (d) hospitals located in a rural area under paragraph (2)(D). At least 1 member shall be knowledgeable in the field of analyzing costs with respect to the provision of inpatient hospital services.

(ii) The Secretary shall make initial appointments to the Board as provided in this paragraph within 180 days after December 19, 1989.

(C)(i) The Board shall consider the application of any subsection (d) hospital requesting that
the Secretary change the hospital's geographic classification for purposes of determining for a fiscal year—

(I) the hospital's average standardized amount under paragraph (2)(D), or

(II) the factor used to adjust the DRG prospective payment rate for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E).

(ii) A hospital requesting a change in geographic classification under clause (i) for a fiscal year shall submit its application to the Board not later than the first day of the 13-month period ending on September 30 of the preceding fiscal year.

(iii)(I) The Board shall render a decision on an application submitted under clause (i) not later than 180 days after the deadline referred to in clause (ii).

(II) Appeal of decisions of the Board shall be subject to the provisions of section 557b of title 5. The Secretary shall issue a decision on such an appeal not later than 90 days after the date on which the appeal is filed. The decision of the Secretary shall be final and shall not be subject to judicial review.

(D)(i) The Secretary shall publish guidelines to be utilized by the Board in rendering decisions on applications submitted under this paragraph, and shall include in such guidelines the following:

(I) Guidelines for comparing wages, taking into account (to the extent the Secretary determines appropriate) occupational mix, in the area in which the hospital is classified and the area in which the hospital is applying to be classified.

(II) Guidelines for determining whether the county in which the hospital is located should be treated as being a part of a particular Metropolitan Statistical Area.

(III) Guidelines for considering information provided by an applicant with respect to the effects of the hospital's geographic classification on access to inpatient hospital services by medicare beneficiaries.

(IV) Guidelines for considering the appropriateness of the criteria used to define New England County Metropolitan Areas.

(ii) Notwithstanding clause (i), if the Secretary uses a method for making adjustments to the DRG prospective payment rate for area differences in hospital wage levels under paragraph (3)(E) that is not based on the use of Metropolitan Statistical Area classifications, the Secretary may revise the guidelines published under clause (i) to the extent such guidelines are used to determine the appropriateness of the geographic area in which the hospital is determined to be located for purposes of making such adjustments.

(iii) Under the guidelines published by the Secretary under clause (i), in the case of a hospital which has ever been classified by the Secretary as a rural referral center under paragraph (5)(C), the Board may not reject the application of the hospital under this paragraph on the basis of any comparison between the average hourly wage of the hospital and the average hourly wage of hospitals in the area in which it is located.

(iv) The Secretary shall publish the guidelines described in clause (i) by July 1, 1990.

(v) Any decision of the Board to reclassify a subsection (d) hospital for purposes of the adjustment factor described in subparagraph (C)(ii)(II) for fiscal year 2001 or any fiscal year thereafter shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of such period.

(vi) Such guidelines shall provide that, in making decisions on applications for reclassification for the purposes described in clause (v) for fiscal year 2003 and any succeeding fiscal year, the Board shall base any comparison of the average hourly wage for the hospital with the average hourly wage for hospitals in an area on—

(1) an average of the average hourly wage amount for the hospital from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys; and

(II) an average of the average hourly wage amount for hospitals in such area from the most recently published hospital wage survey data of the Secretary (as of the date on which the hospital applies for reclassification) and such amount from each of the two immediately preceding surveys.

(E)(i) The Board shall have full power and authority to make rules and establish procedures, not inconsistent with the provisions of this subchapter or regulations of the Secretary, which are necessary or appropriate to carry out the provisions of this paragraph. In the course of any hearing the Board may administer oaths and affirmations. The provisions of subsections (d) and (e) of section 405 of this title with respect to subpenas shall apply to the Board to the same extent as such provisions apply to the Secretary with respect to subchapter II of this chapter.

(II) The Board is authorized to engage such technical assistance and to receive such information as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Board such secretarial, clerical, and other assistance as the Board may require to carry out its functions.

(F)(i) Each member of the Board who is not an officer or employee of the Federal Government shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for grade GS–18 of the General Schedule under section 5332 of title 5 for each day (including travel time) during which such member is engaged in the performance of the duties of the Board. Each member of the Board who is an officer or employee of the United States shall serve without compensation in addition to that received for service as an officer or employee of the United States.

(ii) Members of the Board shall be allowed travel expenses, including per diem in lieu of

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*So in original. Probably should be section "557(b)".*
subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, while away from their homes or regular places of business in the performance of services for the Board.

(11) ADDITIONAL PAYMENTS FOR MANAGED CARE ENROLLEES.—

(A) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1983, the Secretary shall provide for an additional payment amount for each applicable discharge of any subsection (d) hospital that has an approved medical residency training program.

(B) APPLICABLE DISCHARGE.—For purposes of this paragraph, the term “applicable discharge” means the discharge of any individual who is enrolled under a risk-sharing contract with an eligible organization under section 1395mm of this title and who is entitled to benefits under part A of this subchapter or any organization under a Medicare+ Choice organization under part C of this subchapter.

(C) DETERMINATION OF AMOUNT.—The amount of the payment under this paragraph with respect to any applicable discharge shall be equal to the applicable percentage (as defined in subparagraph (A) as follows:

(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-discharge of such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

(iii) In no case shall the applicable percentage increase exceed 25 percent.

(C) DEFINITIONS.—

(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term “low-volume hospital” means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles (or, with respect to fiscal years 2011 and 2012, 15 road miles) from another subsection (d) hospital and has less than 800 discharges (or, with respect to fiscal years 2011 and 2012, 1,600 discharges of individuals entitled to, or enrolled for, benefits under part A) during the fiscal year.

(ii) DISCHARGE.—For purposes of subparagraph (B) and clause (i), the term “discharge” means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A of this subchapter.

(D) TEMPORARY APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2011 and 2012, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.

(12) PAYMENT ADJUSTMENT FOR LOW-VOLUME HOSPITALS.—

(A) IN GENERAL.—In addition to any payments calculated under this section for a subsection (d) hospital, for discharges occurring during a fiscal year (beginning with fiscal year 2005), the Secretary shall provide for an additional payment amount to each low-volume hospital (as defined in subparagraph (C)(i)) for discharges occurring during that fiscal year that is equal to the applicable percentage increase (determined under subparagraph (B) or (D) for the hospital involved) in the amount paid to such hospital under this section for such discharges (determined without regard to this paragraph).

(B) APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2005 through 2010 and for discharges occurring in fiscal year 2013 and subsequent fiscal years, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) as follows:

(i) The Secretary shall determine the empirical relationship for subsection (d) hospitals between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.

(ii) The applicable percentage increase shall be determined based upon such relationship in a manner that reflects, based upon the number of such discharges for a subsection (d) hospital, such additional incremental costs.

(iii) In no case shall the applicable percentage increase exceed 25 percent.

(C) DEFINITIONS.—

(i) LOW-VOLUME HOSPITAL.—For purposes of this paragraph, the term “low-volume hospital” means, for a fiscal year, a subsection (d) hospital (as defined in paragraph (1)(B)) that the Secretary determines is located more than 25 road miles (or, with respect to fiscal years 2011 and 2012, 15 road miles) from another subsection (d) hospital and has less than 800 discharges (or, with respect to fiscal years 2011 and 2012, 1,600 discharges of individuals entitled to, or enrolled for, benefits under part A) during the fiscal year.

(ii) DISCHARGE.—For purposes of subparagraph (B) and clause (i), the term “discharge” means an inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A of this subchapter.

(D) TEMPORARY APPLICABLE PERCENTAGE INCREASE.—For discharges occurring in fiscal years 2011 and 2012, the Secretary shall determine an applicable percentage increase for purposes of subparagraph (A) using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 200 or fewer discharges of individuals entitled to, or enrolled for, benefits under part A in the fiscal year to 0 percent for low-volume hospitals with greater than 1,600 discharges of such individuals in the fiscal year.

(13)(A) In order to recognize commuting patterns among geographic areas, the Secretary shall establish a process through application or otherwise for an increase of the wage index applied under paragraph (3)(E) for subsection (d) hospitals located in a qualifying county described in subparagraph (B) in the amount computed under subparagraph (D) based on out-migration of hospital employees who reside in that county to any higher wage index area.

(B) The Secretary shall establish criteria for a qualifying county under this subparagraph based on the out-migration referred to in subparagraph (A) and differences in the area wage indices. Under such criteria the Secretary shall, utilizing such data as the Secretary determines to be appropriate, establish—

(i) a threshold percentage, established by the Secretary, of the weighted average of the area wage index or indices for the higher wage index areas involved;

(ii) a threshold (of not less than 10 percent) for minimum out-migration to a higher wage index area or areas; and

(iii) a requirement that the average hourly wage of the hospitals in the qualifying county equals or exceeds the average hourly wage of all the hospitals in the area in which the qualifying county is located.

(C) For purposes of this paragraph, the term “higher wage index area” means, with respect to
a county, an area with a wage index that exceeds that of the county.

(D) The increase in the wage index under subparagraph (A) for a qualifying county shall be equal to the percentage of the hospital employees residing in the qualifying county who are employed in any higher wage index area multiplied by the sum of the products, for each higher wage index area of—

(i) the difference between—

(I) the wage index for such higher wage index area, and

(II) the wage index of the qualifying county; and

(ii) the number of hospital employees residing in the qualifying county who are employed in such higher wage index area divided by the total number of hospital employees residing in the qualifying county who are employed in any higher wage index area.

(E) The process under this paragraph may be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10). As the Secretary determines to be appropriate to carry out such process, the Secretary may require hospitals (including subsection (d) hospitals and other hospitals) and critical access hospitals, as required under section 1395ww(a)(1)(T) of this title, to submit data regarding the location of residence, or the Secretary may use data from other sources.

(F) A wage index increase under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to waive the application of such wage index increase.

(G) A hospital in a county that has a wage index increase under this paragraph for a period and that has not waived the application of such an increase under subparagraph (F) is not eligible for reclassification under paragraph (8) or (10) during that period.

(H) Any increase in a wage index under this paragraph for a county shall not be taken into account for purposes of—

(i) computing the wage index for portions of the wage index area (not including the county) in which the county is located; or

(ii) applying any budget neutrality adjustment with respect to such index under paragraph (B)(D).

(I) The thresholds described in subparagraph (B), data on hospital employees used under this paragraph, and any determination of the Secretary under the process described in subparagraph (E) shall be final and shall not be subject to judicial review.

(e) Proportional adjustments in applicable percentage increases

(1)(A) For cost reporting periods of hospitals beginning in fiscal year 1984 or fiscal year 1985, the Secretary shall provide for such proportional adjustment in the applicable percentage increase (otherwise applicable to the periods under subsection (b)(3)(B) of this section) as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(1)(I) of this section for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1395cc(a)(1)(F) of this title), are not greater or less than—

(ii) the target percentage (as defined in subsection (d)(1)(C) of this section) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before April 20, 1983 (excluding payments made under section 1395cc(a)(1)(F) of this title); except that the adjustment made under this subparagraph shall apply only to subsection (d) hospitals and shall not apply for purposes of making computations under subsection (d)(2)(B)(1) of this section or subsection (d)(3)(A) of this section.

(B) For discharges occurring in fiscal year 1984 or fiscal year 1985, the Secretary shall provide under subsections (d)(2)(F) and (d)(3)(C) of this section for such equal proportional adjustment in each of the average standardized amounts otherwise computed for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsection (d)(1)(A)(1)(II) and (d)(5) of this section for that fiscal year for operating costs of inpatient hospital services of hospitals (excluding payments made under section 1395cc(a)(1)(F) of this title), are not greater or less than—

(ii) the DRG percentage (as defined in subsection (d)(1)(C) of this section) of the payment amounts which would have been payable for such services for those same hospitals for that fiscal year under this section under the law as in effect before April 20, 1983 (excluding payments made under section 1395cc(a)(1)(F) of this title).

(C) For discharges occurring in fiscal year 1988, the Secretary shall provide for such equal proportional adjustment in each of the average standardized amounts otherwise computed under subsection (d)(3) of this section for that fiscal year as may be necessary to assure that—

(i) the aggregate payment amounts otherwise provided under subsections (d)(1)(A)(iii), (d)(5), and (d)(9) of this section for that fiscal year for operating costs of inpatient hospital services of subsection (d) hospitals and subsection (d) Puerto Rico hospitals, are not greater or less than—

(ii) the payment amounts that would have been payable for such services for those same hospitals for that fiscal year but for the enactment of the amendments made by section 9304 of the Omnibus Budget Reconciliation Act of 1986.


(4) Taking into consideration the recommendations of the Commission, the Secretary shall recommend for each fiscal year (beginning with fiscal year 1988) an appropriate change fac-
tor for inpatient hospital services for discharges in that fiscal year which will take into account amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. The appropriate change factor may be different for all large urban subsection (d) hospitals, other urban subsection (d) hospitals, urban subsection (d) Puerto Rico hospitals, rural subsection (d) hospitals, and rural subsection (d) Puerto Rico hospitals, and all other hospitals and units not paid under subsection (d) of this section, and may vary among such other hospitals and units.

(B) In addition to the recommendation made under subparagraph (A), the Secretary shall, taking into consideration the recommendations of the Commission under paragraph (2)(B), recommend for each fiscal year (beginning with fiscal year 1992) other appropriate changes in each existing reimbursement policy under this subchapter under which payments to an institution are based upon prospectively determined rates.

(5) The Secretary shall cause to have published in the Federal Register, not later than June 30 of the April 1 before each fiscal year (beginning with fiscal year 1986), the Secretary’s proposed recommendations under paragraph (4) for that fiscal year for public comment, and shall place into effect a standardized electronic payment rate in effect on September 30, 1995 shall be reduced in a manner that results in a 7.4 percent the unadjusted standard Federal capital payment rate (as described in 42 CFR 412.335(c), as in effect on September 30, 1995) other appropriate changes in each existing reimbursement policy under this subchapter under which payments to an institution are based upon prospectively determined rates.

(f) Reporting of costs of hospitals receiving payments on basis of prospective rates

(1)(A) The Secretary shall maintain a system for the reporting of costs of hospitals receiving payments computed under subsection (d) of this section.

(B)(i) Subject to clause (ii), the Secretary shall place into effect a standardized electronic cost reporting format for hospitals under this subchapter.

(ii) The Secretary may delay or waive the implementation of such format in particular instances where such implementation would result in financial hardship (in particular with respect to hospitals with a small percentage of inpatients entitled to benefits under this subchapter).

(2) If the Secretary determines, based upon information supplied by a utilization and quality control peer review organization under part B of subchapter XI of this chapter, that a hospital, in order to circumvent the payment methodology established under subsection (b) or (d) of this section, has taken an action that results in the admission of individuals entitled to benefits under part A unnecessarily, unnecessary multiple admissions of the same such individuals, or other inappropriate medical or other practices with respect to such individuals, the Secretary may—

(A) deny payment (in whole or in part) under part A of this subchapter with respect to inpatient hospital services provided with respect to such an unnecessary admission (or subsequent admission of the same individual), or

(B) require the hospital to take other corrective action necessary to prevent or correct the inappropriate practice.

(3) The provisions of subsections (c) through (g) of section 1320a–7 of this title shall apply to determinations made under paragraph (2) in the same manner as they apply to exclusions effected under section 1320a–7(b)(13) of this title.

(g) Prospective payment for capital-related costs; return on equity capital for hospitals

(1)(A) Notwithstanding section 1395x(v) of this title, instead of any amounts that are otherwise payable under this subchapter with respect to the reasonable costs of subsection (d) hospitals and subsection (d) Puerto Rico hospitals for capital-related costs of inpatient hospital services, the Secretary shall, for hospital cost reporting periods beginning on or after October 1, 1991, provide for payments for such costs in accordance with a prospective payment system established by the Secretary.

(2) If the Secretary determines, based upon information supplied by a utilization and quality control peer review organization under part B of subchapter XI of this chapter, that a hospital, in order to circumvent the payment methodology established under subsection (b) or (d) of this section, has taken an action that results in the admission of individuals entitled to benefits under part A unnecessarily, unnecessary multiple
(ii) may provide for an adjustment to take into account variations in the relative costs of capital and construction for the different types of facilities or areas in which they are located;

(iii) may provide for such exceptions (including appropriate exceptions to reflect capital obligations) as the Secretary determines to be appropriate, and

(iv) may provide for suitable adjustment to reflect hospital occupancy rate.

(C) In this paragraph, the term "capital-related costs" has the meaning given such term by the Secretary under subsection (a)(4) of this section as of September 30, 1987, and does not include a return on equity capital.

(2)(A) The Secretary shall provide that the amount which is allowable, with respect to reasonable costs of inpatient hospital services for which payment may be made under this subchapter, for a return on equity capital for hospitals shall, for cost reporting periods beginning on or after April 20, 1983, be equal to amounts otherwise allowable under regulations in effect on March 1, 1983, except that the rate of return to be recognized shall be equal to the applicable percentage (described in subparagraph (B)) of the average of the rates of interest, for each of the months any part of which is included in the reporting period, on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

(B) In this paragraph, the "applicable percentage" is—

(i) 75 percent, for cost reporting periods beginning during fiscal year 1987,

(ii) 50 percent, for cost reporting periods beginning during fiscal year 1988,

(iii) 25 percent, for cost reporting periods beginning during fiscal year 1989, and

(iv) 0 percent, for cost reporting periods beginning on or after October 1, 1989.

(3)(A) Except as provided in subparagraph (B), in determining the amount of the payments that may be made under this subchapter with respect to all the capital-related costs of inpatient hospital services of a subsection (d) hospital and a subsection (d) Puerto Rico hospital, the Secretary shall reduce the amounts of such payments otherwise established under this subchapter by—

(i) 3.5 percent for payments attributable to portions of cost reporting periods occurring during fiscal year 1987,

(ii) 7 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988 on or after October 1, 1987, and before January 1, 1988,

(iii) 12 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) in fiscal year 1988, occurring on or after January 1, 1988,

(iv) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1989, and

(v) 15 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during the period beginning January 1, 1990, and ending September 30, 1991.

(B) Subparagraph (A) shall not apply to payments with respect to the capital-related costs of any hospital that is a sole community hospital (as defined in subsection (d)(5)(D)(iii) of this section) or a critical access hospital (as defined in section 1395x(mm)(1) of this title).

(4) In determining the amount of the payments that are attributable to portions of cost reporting periods occurring during fiscal years 1998 through 2002 and that may be made under this subchapter with respect to capital-related costs of inpatient hospital services of a hospital which is described in clause (i), (ii), or (iv) of subsection (d)(1)(B) of this section or a unit described in the matter after clause (v) of such subsection, the Secretary shall reduce the amounts of such payments otherwise determined under this subchapter by 15 percent.

(h) Payments for direct graduate medical education costs

(1) Substitution of special payment rules

Notwithstanding section 1395x(v) of this title, instead of any amounts that are otherwise payable under this subchapter with respect to the reasonable costs of hospitals for direct graduate medical education costs, the Secretary shall provide for payments for such costs in accordance with paragraph (3) of this subsection. In providing for such payments, the Secretary shall provide for an allocation of such payments between part A and part B of this subchapter (and the trust funds established under the respective parts) as reasonably reflects the proportion of direct graduate medical education costs of hospitals associated with the provision of services under each respective part.

(2) Determination of hospital-specific approved FTE resident amounts

The Secretary shall determine, for each hospital with an approved medical residency training program, an approved FTE resident amount for each cost reporting period beginning on or after July 1, 1985, as follows:

(A) Determining allowable average cost per FTE resident in a hospital's base period

The Secretary shall determine, for the hospital's cost reporting period that began during fiscal year 1984, the average amount recognized as reasonable under this subchapter for direct graduate medical education costs of the hospital for each full-time-equivalent resident.

(B) Updating to the first cost reporting period

(i) In general

The Secretary shall update each average amount determined under subparagraph (A) by the percentage increase in the consumer price index during the 12-month cost reporting period described in such subparagraph.

(ii) Exception

The Secretary shall not perform an update under clause (i) in the case of a hos-
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The hospital if the hospital’s reporting period, described in subparagraph (A), began on or after July 1, 1984, and before October 1, 1984.

(C) Amount for first cost reporting period

For the first cost reporting period of the hospital beginning on or after July 1, 1985, the approved FTE resident amount for the hospital is equal to the amount determined under subparagraph (B) increased by 1 percent.

(D) Amount for subsequent cost reporting periods

(i) In general

Except as provided in a subsequent clause, for each subsequent cost reporting period, the approved FTE resident amount for the hospital is equal to the approved FTE resident amount determined under this paragraph for the previous cost reporting period updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index during the 12-month period ending at that midpoint, with appropriate adjustments to reflect previous under- or over-estimations under this subparagraph in the projected percentage change in the consumer price index.

(ii) Freeze in update for fiscal years 1994 and 1995

For cost reporting periods beginning during fiscal year 1994 or fiscal year 1995, the approved FTE resident amount for a hospital shall not be updated under clause (i) for a resident who is not a primary care resident (as defined in paragraph (5)(H)) or a resident enrolled in an approved medical residency training program in obstetrics and gynecology.

(iii) Floor for locality adjusted national average per resident amount

The approved FTE resident amount for a hospital for the cost reporting period beginning during fiscal year 2001 shall not be less than 70 percent, and for the cost reporting period beginning during fiscal year 2002 shall not be less than 85 percent, of the locality adjusted national average per resident amount computed under subparagraph (E) for the hospital and period.

(iv) Adjustment in rate of increase for hospitals with FTE approved amount above 140 percent of locality adjusted national average per resident amount

(I) Freeze for fiscal years 2001 and 2002 and 2004 through 2013

For a cost reporting period beginning during fiscal year 2001 or fiscal year 2002 or during the period beginning with fiscal year 2004 and ending with fiscal year 2013, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and period, subject to subclause (III), the approved FTE resident amount for the period involved shall be the same as the approved FTE resident amount for the hospital for such preceding cost reporting period.

(II) 2 percent decrease in update for fiscal years 2003, 2004, and 2005

For the cost reporting period beginning during fiscal year 2003, if the approved FTE resident amount for a hospital for the preceding cost reporting period exceeds 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for that hospital and preceding period, the approved FTE resident amount for the period involved shall be updated in the manner described in subparagraph (D)(i) except that, subject to subclause (III), the consumer price index applied for a 12-month period shall be reduced (but not below zero) by 2 percentage points.

(III) No adjustment below 140 percent

In no case shall subclause (I) or (II) reduce an approved FTE resident amount for a hospital for a cost reporting period below 140 percent of the locality adjusted national average per resident amount computed under subparagraph (E) for such hospital and period.

(E) Determination of locality adjusted national average per resident amount

The Secretary shall determine a locality adjusted national average per resident amount with respect to a cost reporting period of a hospital beginning during a fiscal year as follows:

(i) Determining hospital single per resident amount

The Secretary shall compute for each hospital operating an approved graduate medical education program a single per resident amount equal to the average (weighted by number of full-time equivalent residents, as determined under paragraph (4)) of the primary care per resident amount and the non-primary care per resident amount computed under paragraph (2) for cost reporting periods ending during fiscal year 1997.

(ii) Standardizing per resident amounts

The Secretary shall compute a standardized per resident amount for each such hospital by dividing the single per resident amount computed under clause (i) by an average of the 3 geographic index values (weighted by the national average weight for each of the work, practice expense, and malpractice components) as applied under section 1395w–4(e) of this title for 1999 for the fee schedule area in which the hospital is located.

(iii) Computing of weighted average

The Secretary shall compute the average of the standardized per resident amounts
computed under clause (ii) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital (as determined under paragraph (4)).

(iv) Computing national average per resident amount

The Secretary shall compute the national average per resident amount, for a hospital’s cost reporting period that begins during fiscal year 2001, equal to the weighted average computed under clause (iii) increased by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning with the month that represents the midpoint of the cost reporting periods described in clause (i) and ending with the midpoint of the hospital’s cost reporting period that begins during fiscal year 2001.

(v) Adjusting for locality

The Secretary shall compute the product of—

(I) the national average per resident amount computed under clause (iv) for the hospital, and

(II) the geographic index value average (described and applied under clause (ii)) for the fee schedule area in which the hospital is located.

(vi) Computing locality adjusted amount

The locality adjusted national per resident amount for a hospital for—

(I) the cost reporting period beginning during fiscal year 2001 is the product computed under clause (v); or

(II) each subsequent cost reporting period is equal to the locality adjusted national per resident amount for the hospital for the previous cost reporting period (as determined under this clause) updated, through the midpoint of the period, by projecting the estimated percentage change in the consumer price index for all urban consumers during the 12-month period ending at that midpoint.

(F) Treatment of certain hospitals

In the case of a hospital that did not have an approved medical residency training program or was not participating in the program under this subchapter for a cost reporting period beginning during fiscal year 1984, the Secretary shall, for the first such period for which it has such a residency training program and is participating under this subchapter, provide for such approved FTE resident amount as the Secretary determines to be appropriate, based on approved FTE resident amounts for comparable programs.

(3) Hospital payment amount per resident

(A) In general

The payment amount, for a hospital cost reporting period beginning on or after July 1, 1985, is equal to the product of—

(i) the aggregate approved amount (as defined in subparagraph (B)) for that period, and

(ii) the hospital’s medicare patient load (as defined in subparagraph (C)) for that period.

(B) Aggregate approved amount

As used in subparagraph (A), the term “aggregate approved amount” means, for a hospital cost reporting period, the product of—

(i) the hospital’s approved FTE resident amount (determined under paragraph (2)) for that period, and

(ii) the weighted average number of full-time-equivalent residents (as determined under paragraph (4)) in the hospital’s approved medical residency training programs in that period.

The Secretary shall reduce the aggregate approved amount to the extent payment is made under subsection (k) of this section for residents included in the hospital’s count of full-time-equivalent residents.

(C) Medicare patient load

As used in subparagraph (A), the term “medicare patient load” means, with respect to a hospital’s cost reporting period, the fraction of the total number of inpatient-bed days (as established by the Secretary) during the period which are attributable to patients with respect to whom payment may be made under part A of this subchapter.

(D) Payment for managed care enrollees

(i) In general

For portions of cost reporting periods occurring on or after January 1, 1998, the Secretary shall provide for an additional payment amount under this subsection for services furnished to individuals who are enrolled under a risk-sharing contract with an eligible organization under section 1395mm of this title and who are entitled to part A of this subchapter or with a Medicare+Choice organization under part C of this subchapter. The amount of such a payment shall equal, subject to clause (iii), the applicable percentage of the product of—

(I) the aggregate approved amount (as defined in subparagraph (B)) for that period; and

(II) the fraction of the total number of inpatient-bed days (as established by the Secretary) during the period which are attributable to such enrolled individuals.

(ii) Applicable percentage

For purposes of clause (i), the applicable percentage is—

(I) 20 percent in 1998,

(II) 40 percent in 1999,

(III) 60 percent in 2000,

(IV) 80 percent in 2001, and

(V) 100 percent in 2002 and subsequent years.

(iii) Proportional reduction for nursing and allied health education

The Secretary shall estimate a proportional adjustment in payments to all hospitals determined under clauses (i) and (ii) for portions of cost reporting periods be-
beginning in a year (beginning with 2000) such that the proportional adjustment reduces payments in an amount for such year equal to the total additional payment amounts for nursing and allied health education determined under the application of this section for portions of cost reporting periods occurring in that year.

(iv) Special rule for hospitals under reimbursement system

The Secretary shall establish rules for the application of this subparagraph to a hospital reimbursed under a reimbursement system authorized under section 1395f(b)(3) of this title in the same manner as it would apply to the hospital if it were not reimbursed under such section.

(4) Determination of full-time-equivalent residents

(A) Rules

The Secretary shall establish rules consistent with this paragraph for the computation of the number of full-time-equivalent residents in an approved medical residency training program.

(B) Adjustment for part-year or part-time residents

Such rules shall take into account individuals who serve as residents for only a portion of a period with a hospital or simultaneously with more than one hospital.

(C) Weighting factors for certain residents

Subject to subparagraph (D), such rules shall provide, in calculating the number of full-time-equivalent residents in an approved residency program:

(i) before July 1, 1986, for each resident the weighting factor is 1.00;

(ii) on or after July 1, 1986, for a resident who is in the resident’s initial residency period (as defined in paragraph (5)(F)), the weighting factor is 1.00;

(iii) on or after July 1, 1986, and before July 1, 1987, for a resident who is not in the resident’s initial residency period (as defined in paragraph (5)(F)), the weighting factor is .75, and

(iv) on or after July 1, 1987, for a resident who is not in the resident’s initial residency period (as defined in paragraph (5)(F)), the weighting factor is .50.

(D) Foreign medical graduates required to pass FMGEMS examination

(i) In general

Except as provided in clause (ii), such rules shall provide that, in the case of an individual who is a foreign medical graduate (as defined in paragraph (5)(D)), the individual shall not be counted as a resident on or after July 1, 1986, unless—

(I) the individual has passed the FMGEMS examination (as defined in paragraph (5)(E)), or

(II) the individual has previously received certification from, or has previously passed the examination of, the Educational Commission for Foreign Medical Graduates.

(ii) Transition for current FMGS

On or after July 1, 1986, but before July 1, 1987, in the case of a foreign medical graduate who—

(I) has served as a resident before July 1, 1986, and is serving as a resident after that date, but

(II) has not passed the FMGEMS examination or a previous examination of the Educational Commission for Foreign Medical Graduates before July 1, 1986, the individual shall be counted as a resident at a rate equal to one-half of the rate at which the individual would otherwise be counted.

(E) Counting time spent in outpatient settings

Subject to subparagraphs (J) and (K), such rules shall provide that only time spent in activities relating to patient care shall be counted and that—

(i) effective for cost reporting periods beginning before July 1, 2010, all the time;9 so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting; and

(ii) effective for cost reporting periods beginning on or after July 1, 2010, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if a hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.

Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.

(F) Limitation on number of residents in allopathic and osteopathic medicine

(i) In general

Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, subject to paragraphs (7) and (8), the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital’s approved medical residency training program in the fields of allopathic...
(H) Special rules for application of subparagraphs (F) and (G)

(i) New facilities

The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to paragraphs (7) and (8), prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give special consideration to facilities that meet the needs of underserved rural areas.

(ii) Aggregation

The Secretary may prescribe rules which allow institutions which are members of the same affiliated group (as defined by the Secretary) to elect to apply the limitation of subparagraph (F) on an aggregate basis.

(iii) Data collection

The Secretary may require any entity that operates a medical residency training program and to which subparagraphs (F) and (G) apply to submit to the Secretary such additional information as the Secretary considers necessary to carry out such subparagraphs.

(iv) Nonrural hospitals operating training programs in rural areas

In the case of a hospital that is not located in a rural area but establishes separately accredited approved medical residency training programs (or rural tracks) in an\textsuperscript{10} rural area or has an accredited training program with an integrated rural track, the Secretary shall adjust the limitation under subparagraph (F) in an appropriate manner insofar as it applies to such programs in rural areas in order to encourage the training of physicians in rural areas.

(v) Special provider agreement

If an entity enters into a provider agreement pursuant to section 1395cc(a) of this title to provide hospital services on the same physical site previously used by Medicare Provider No. 05–0578—

(I) the limitation on the number of total full time equivalent residents under subparagraph (F) and clauses (v) and (vi)(I) of subsection (d)(5)(B) applicable to such provider shall be equal to the limitation applicable under such provisions to Provider No. 05–0578 for its cost reporting period ending on June 30, 2006; and

(II) the provisions of subparagraph (G) and subsection (d)(5)(B)(vi)(II) shall not be applicable to such provider for the first three cost reporting years in which such provider trains residents under any approved medical residency training program.

(vi) Redistribution of residency slots after a hospital closes

(I) In general

Subject to the succeeding provisions of this clause, the Secretary shall, by regulation, establish a process under which, in the case where a hospital (other than a hospital described in clause (v)) with
an approved medical residency program closes on or after a date that is 2 years before March 23, 2010, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in accordance with this clause.

(II) Priority for hospitals in certain areas

Subject to the succeeding provisions of this clause, in determining for which hospitals the increase in the otherwise applicable resident limit is provided under such process, the Secretary shall distribute the increase to hospitals in the following priority order (with preference given within each category to hospitals that are members of the same affiliated group (as defined by the Secretary under clause (ii)) as the closed hospital):

(aaa) First, to hospitals located in the same core-based statistical area as, or a core-based statistical area contiguous to, the hospital that closed.

(bb) Second, to hospitals located in the same State as the hospital that closed.

(cc) Third, to hospitals located in the same region of the country as the hospital that closed.

(dd) Fourth, only if the Secretary is not able to distribute the increase to hospitals described in item (cc), to qualifying hospitals in accordance with the provisions of paragraph (8).

(III) Requirement hospital likely to fill position within certain time period

The Secretary may only increase the otherwise applicable resident limit of a hospital under such process if the Secretary determines the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.

(IV) Limitation

The aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

(V) Administration

Chapter 35 of title 44 shall not apply to the implementation of this clause.

(J) Treatment of certain nonprovider and didactic activities

Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.

(K) Treatment of certain other activities

In determining the hospital’s number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.

(5) Definitions and special rules

As used in this subsection:

(A) Approved medical residency training program

The term “approved medical residency training program” means a residency or other postgraduate medical training program participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary.

(B) Consumer price index

The term “consumer price index” refers to the Consumer Price Index for All Urban Consumers (United States city average), as published by the Secretary of Commerce.

(C) Direct graduate medical education costs

The term “direct graduate medical education costs” means direct costs of approved educational activities for approved medical residency training programs.

(D) Foreign medical graduate

The term “foreign medical graduate” means a resident who is not a graduate of—

(i) a school of medicine accredited by the Liaison Committee on Medical Education of the American Medical Association and the Association of American Medical Colleges (or approved by such Committee as meeting the standards necessary for such accreditation),

(ii) a school of osteopathy accredited by the American Osteopathic Association, or approved by such Association as meeting the standards necessary for such accreditation, or

(iii) a school of dentistry or podiatry which is accredited (or meets the standards for accreditation) by an organization recognized by the Secretary for such purpose.

(E) FMGEMS examination

The term “FMGEMS examination” means parts I and II of the Foreign Medical Graduate Examination in the Medical Sciences or any successor examination recognized by the Secretary for this purpose.

(F) Initial residency period

The term “initial residency period” means the period of board eligibility, except that—

11 So in original. No subpar. (I) has been enacted.
(i) except as provided in clause (ii), in no case shall the initial period of residency exceed an aggregate period of formal training of more than five years for any individual, and

(ii) a period of not more than two years, during which an individual is in a geriatric residency or fellowship program or a preventive medicine residency or fellowship program which meets such criteria as the Secretary may establish, shall be treated as part of the initial residency period, but shall not be counted against any limitation on the initial residency period.

Subject to subparagraph (G)(v), the initial residency period shall be determined, with respect to a resident, as of the time the resident enters the residency training program.

(G) Period of board eligibility

(i) General rule

Subject to clauses (ii), (iii), (iv), and (v), the term “period of board eligibility” means, for a resident, the minimum number of years of formal training necessary to satisfy the requirements for initial board eligibility in the particular specialty for which the resident is training.

(ii) Application of 1985-1986 directory

Except as provided in clause (iii), the period of board eligibility shall be such period specified in the 1985–1986 Directory of Residency Training Programs published by the Accreditation Council on Graduate Medical Education.

(iii) Changes in period of board eligibility

On or after July 1, 1989, if the Accreditation Council on Graduate Medical Education, in its Directory of Residency Training Programs—

(I) increases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, above the period specified in its 1985–1986 Directory, the Secretary may increase the period of board eligibility for that specialty, but not to exceed the period of board eligibility specified in that later Directory; or

(II) decreases the minimum number of years of formal training necessary to satisfy the requirements for a specialty, below the period specified in its 1985–1986 Directory, the Secretary may decrease the period of board eligibility for that specialty, but not below the period of board eligibility specified in that later Directory.

(iv) Special rule for certain primary care combined residency programs

(I) In the case of a resident enrolled in a combined medical residency training program in which all of the individual programs (that are combined) are for training a primary care resident (as defined in subparagraph (H)), the period of board eligibility shall be the minimum number of years of formal training required to satisfy the requirements for initial board eligibility in the longest of the individual programs plus one additional year.

(II) A resident enrolled in a combined medical residency training program that includes an obstetrics and gynecology program shall qualify for the period of board eligibility under subclause (I) if the other programs such resident combines with such obstetrics and gynecology program are for training a primary care resident.

(v) Child neurology training programs

In the case of a resident enrolled in a child neurology residency training program, the period of board eligibility and the initial residency period shall be the period of board eligibility for pediatrics plus 2 years.

(H) Primary care resident

The term “primary care resident” means a resident enrolled in an approved medical residency training program in family medicine, general internal medicine, general pediatrics, preventive medicine, geriatric medicine, or osteopathic general practice.

(i) Resident

The term “resident” includes an intern or other participant in an approved medical residency training program.

(J) Adjustments for certain family practice residency programs

(i) In general

In the case of an approved medical residency training program (meeting the requirements of clause (ii)) of a hospital which received funds from the United States, a State, or a political subdivision of a State or an instrumentality of such a State or political subdivision (other than payments under this subchapter or a State plan under subchapter XIX of this chapter) for the program during the cost reporting period that began during fiscal year 1984, the Secretary shall—

(I) provide for an average amount under paragraph (2)(A) that takes into account the Secretary’s estimate of the amount that would have been recognized as reasonable under this subchapter if the hospital had not received such funds, and

(II) reduce the payment amount otherwise provided under this subsection in an amount equal to the proportion of such program funds received during the cost reporting period involved that is allocable to this subchapter.

(ii) Additional requirements

A hospital’s approved medical residency program meets the requirements of this clause if—

(I) the program is limited to training for family and community medicine;

(II) the program is the only approved medical residency program of the hospital; and

(III) the average amount determined under paragraph (2)(A) for the hospital
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Incentive payment under plans for voluntary reduction in number of residents

(A) In general

In the case of a voluntary residency reduction plan for which an application is approved under subparagraph (B), subject to subparagraph (F), each hospital which is part of the qualifying entity submitting the plan shall be paid an applicable hold harmless percentage (as specified in subparagraph (E)) of the sum of—

(i) the amount (if any) by which—

(I) the amount of payment which would have been made under this subsection if there had been a 5-percent reduction in the number of full-time equivalent residents in the approved medical education training programs of the hospital as of June 30, 1997, exceeds

(II) the amount of payment which is made under this subsection, taking into account the reduction in such number effected under the reduction plan; and

(ii) the amount of the reduction in payment under subsection (d)(5)(B) of this section for the hospital that is attributable to the reduction in number of residents effected under the plan below 95 percent of the number of full-time equivalent residents in such programs of the hospital as of June 30, 1997.

The determination of the amounts under clauses (i) and (ii) for any year shall be made on the basis of the provisions of this subchapter in effect on the application deadline date for the first calendar year to which the reduction plan applies.

(B) Approval of plan applications

The Secretary may not approve the application of an qualifying entity unless—

(i) the application is submitted in a form and manner specified by the Secretary and by not later than November 1, 1999; 12

(ii) the application provides for the operation of a plan for the reduction in the number of full-time equivalent residents in the approved medical residency training programs of the entity consistent with the requirements of subparagraph (D);

(iii) the entity elects in the application the period of residency training years (not greater than 5) over which the reduction will occur;

(iv) the entity will not reduce the proportion of its residents in primary care (to the total number of residents) below such proportion as in effect as of the applicable time described in subparagraph (D)(v); and

(v) the Secretary determines that the application and the entity and such plan meet such other requirements as the Secretary specifies in regulations.

(C) Qualifying entity

For purposes of this paragraph, any of the following may be a qualifying entity:

(i) Individual hospitals operating one or more approved medical residency training programs.

(ii) Two or more hospitals that operate such programs and apply for treatment under this paragraph as a single qualifying entity.

(iii) A qualifying consortium (as described in section 4628 of the Balanced Budget Act of 1997).

(D) Residency reduction requirements

(i) Individual hospital applicants

In the case of a qualifying entity described in subparagraph (C)(i), the number of full-time equivalent residents in all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) If the base number of residents exceeds 750 residents, by a number equal to at least 20 percent of such base number.

(II) Subject to subclause (IV), if the base number of residents exceeds 600 but is less than 750 residents, by 150 residents.

(III) Subject to subclause (IV), if the base number of residents does not exceed 600 residents, by a number equal to at least 25 percent of such base number.

(IV) In the case of a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(ii) Joint applicants

In the case of a qualifying entity described in subparagraph (C)(ii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced as follows:

(I) Subject to subclause (II), by a number equal to at least 25 percent of the base number.

(II) In the case of such a qualifying entity which is described in clause (v) and which elects treatment under this subclause, by a number equal to at least 20 percent of the base number.

(iii) Consortia

In the case of a qualifying entity described in subparagraph (C)(iii), the number of full-time equivalent residents in the aggregate for all the approved medical residency training programs operated by or through the entity shall be reduced by a number equal to at least 20 percent of the base number.

12So in original. The comma probably should be a semicolon.
(iv) Manner of reduction

The reductions specified under the preceding provisions of this subparagraph for a qualifying entity shall be below the base number of residents for that entity and shall be fully effective not later than the 5th residency training year in which the application under subparagraph (B) is effective.

(v) Entities providing assurance of increase in primary care residents

An entity is described in this clause if—
(I) the base number of residents for the entity is less than 750 or the entity is described in subparagraph (C)(ii); and
(II) the entity represents in its application under subparagraph (B) that it will increase the number of full-time equivalent residents in primary care by at least 20 percent (from such number included in the base number of residents) by not later than the 5th residency training year in which the application under subparagraph (B) is effective.

If a qualifying entity fails to comply with the representation described in subclause (II) by the end of such 5th residency training year, the entity shall be subject to repayment of all amounts paid under this paragraph, in accordance with procedures established to carry out subparagraph (F).

(vi) “Base number of residents” defined

For purposes of this paragraph, the term “base number of residents” means, with respect to a qualifying entity (or its participating hospitals) operating approved medical residency training programs, the number of full-time equivalent residents in such programs (before application of weighting factors) of the entity as of the most recent residency training year ending before June 30, 1997, or, if less, for any subsequent residency training year that ends before the date the entity makes application under this paragraph.

(E) Applicable hold harmless percentage

For purposes of subparagraph (A), the “applicable hold harmless percentage” for the—
(I) first and second residency training years in which the reduction plan is in effect, 100 percent,
(ii) third such year, 75 percent,
(iii) fourth such year, 50 percent, and
(iv) fifth such year, 25 percent.

(F) Penalty for noncompliance

(i) In general

No payment may be made under this paragraph to a hospital for a residency training year if the hospital has failed to reduce the number of full-time equivalent residents (in the manner required under subparagraph (D)) to the number agreed to by the Secretary and the qualifying entity in approving the application under this paragraph with respect to such year.

(ii) Increase in number of residents in subsequent years

If payments are made under this paragraph to a hospital, and if the hospital increases the number of full-time equivalent residents above the number of such residents permitted under the reduction plan as of the completion of the plan, then, as specified by the Secretary, the entity is liable for repayment to the Secretary of the total amounts paid under this paragraph to the entity.

(G) Treatment of rotating residents

In applying this paragraph, the Secretary shall establish rules regarding the counting of residents who are assigned to institutions the medical residency training programs in which are not covered under approved applications under this paragraph.

(7) Redistribution of unused resident positions

(A) Reduction in limit based on unused positions

(i) Programs subject to reduction

In general

Except as provided in subclause (II), if a hospital’s reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2005, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(II) Exception for small rural hospitals

This subparagraph shall not apply to a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii) of this section) with fewer than 250 acute care inpatient beds.

(ii) Reference resident level

(I) In general

Except as otherwise provided in subclauses (II) and (III), the reference resident level specified in this clause for a hospital is the resident level for the most recent cost reporting period of the hospital ending on or before September 30, 2002, for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(II) Use of most recent accounting period to recognize expansion of existing programs

If a hospital submits a timely request to increase its resident level due to an expansion of an existing residency training program that is not reflected on the most recent cost report, after audit and subject to the discretion of the Secretary, the reference resident level for such hospital is the resident level for the cost reporting period that includes July 1, 2003, as determined by the Secretary.

(III) Expansions under newly approved programs

Upon the timely request of a hospital, the Secretary shall adjust the reference
residency level specified under subclause (I) or (II) to include the number of medical residents that were approved in an application for a medical residency training program that was approved by an appropriate accrediting organization (as determined by the Secretary) before January 1, 2002, but which was not in operation during the cost reporting period used under subclause (I) or (II), as the case may be, as determined by the Secretary.

(iii) Affiliation

The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) as of July 1, 2003.

(B) Redistribution

(i) In general

The Secretary is authorized to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2005. The aggregate number of increases in the otherwise applicable resident limits under this subparagraph may not exceed the Secretary’s estimate of the aggregate reduction in such limits attributable to subparagraph (A).

(ii) Considerations in redistribution

In determining for which hospitals the increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2005, made available under this subparagraph, as determined by the Secretary.

(iii) Priority for rural and small urban areas

In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under clause (i), the Secretary shall distribute the increase to programs of hospitals located in the following priority order:

(I) First, to hospitals located in rural areas (as defined in subsection (d)(2)(D)(i) of this section).

(II) Second, to hospitals located in urban areas that are not large urban areas (as defined for purposes of subsection (d) of this section).

(III) Third, to other hospitals in a State if the residency training program involved is in a specialty for which there are not other residency training programs in the State.

Increases of residency limits within the same priority category under this clause shall be determined by the Secretary.

(iv) Limitation

In no case shall more than 25 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

(v) Application of locality adjusted national average per resident amount

With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under paragraph (4)(E) for that hospital.

(vi) Construction

Nothing in this subparagraph shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6), under a demonstration project approved as of October 31, 2003, under the authority of section 402 of Public Law 90–248, or as affecting the ability of a hospital to establish new medical residency training programs under paragraph (4)(H).

(C) Resident level and limit defined

In this paragraph:

(i) Resident level

The term “resident level” means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under paragraph (4)), in the fields of allopathic and osteopathic medicine for the hospital.

(ii) Otherwise applicable resident limit

The term “otherwise applicable resident limit” means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph.

(D) Adjustment based on settled cost report

In the case of a hospital with a dual accredited osteopathic and allopathic family practice program for which—

(i) the otherwise applicable resident limit was reduced under subparagraph (A)(i)(I); and

(ii) such reduction was based on a reference resident level that was determined using a cost report and where a revised or corrected notice of program reimbursement was issued for such cost report between September 1, 2006 and September 15, 2006, whether as a result of an appeal or otherwise, and the reference resident level under such settled cost report is higher than the level used for the reduction under subparagraph (A)(i)(I);

the Secretary shall apply subparagraph (A)(i)(I) using the higher resident reference level and make any necessary adjustments
(B) Distribution

(i) In general

The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2011. The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the aggregate reduction in such limits attributable to such reduction in accordance with the requirements of this subparagraph (A) (as estimated by the Secretary).

(ii) Requirements

Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident limit under this subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that—

(I) the number of full-time equivalent primary care residents, as defined in paragraph (4)(H)(v) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to March 23, 2010; and

(II) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.

(iii) Redistribution of positions if hospital no longer meets certain requirements

In the case where the Secretary determines that a hospital described in clause (ii) does not meet either of the requirements under subclause (I) or (II) of such clause, the Secretary shall—

(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and

(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

(C) Considerations in redistribution

In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), the Secretary shall take into account—

(i) the demonstration likelihood of the hospital filling the positions made available under this paragraph within the first 3 cost reporting periods beginning on or after July 1, 2011, as determined by the Secretary; and

(ii) whether the hospital has an accredited rural training track (as described in paragraph (4)(H)(iv)).

(D) Priority for certain areas

In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), subject to subparagraph (E), the Secretary shall distribute the increase to hospitals based on the following factors:

(i) Whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile (as determined by the Secretary).

(ii) Whether the hospital is located in a State, a territory of the United States, or the District of Columbia that is among the top 10 States, territories, or Districts in terms of the ratio of—

(I) the total population of the State, territory, or District living in an area designated (under such section 332(a)(1)(A)) as a health professional shortage area (as of the date of enactment of this paragraph); and

(II) the number of full-time equivalent primary care residents, as defined in paragraph (4)(H)(v) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to March 23, 2010; and

(III) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.

(E) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395s(aa) of this title, or otherwise, with respect to determinations made under this title, or otherwise, with respect to determinations made under this

(E) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395s(aa) of this title, or otherwise, with respect to determinations made under this title, or otherwise, with respect to determinations made under this
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(G) Application of per resident amounts for primary care and nonprimary care

With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

(H) Definitions

In this paragraph:

(i) Reference resident level

The term “reference resident level” means, with respect to a hospital, the highest resident level for any of the 3 most recent cost reporting periods (ending before March 23, 2010) of the hospital for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(ii) Resident level

The term “resident level” has the meaning given such term in paragraph (7)(C)(i).

(iii) Otherwise applicable resident limit

The term “otherwise applicable resident limit” means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).

(I) Affiliation

The provisions of this paragraph shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and the reference resident level for each such hospital shall be the reference resident level with respect to the cost reporting period that results in the smallest difference between the reference resident level and the otherwise applicable resident limit.

(ii) Exception if positions not redistributed by July 1, 2011

In the case where the Secretary does not distribute positions to hospitals in accordance with clause (i) by July 1, 2011, the Secretary shall distribute such positions to other hospitals in accordance with the considerations described in subparagraph (C) and the priority described in subparagraph (D).

(F) Limitation

A hospital may not receive more than 75 full-time equivalent additional residency positions under this paragraph.

(B) Fully implemented system

Notwithstanding section 1395f(b) of this title, but subject to the provisions of section 1395e of this title, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation hospital or a rehabilitation unit (in this subsection referred to as a “rehabilitation facility”), other than a facility making an election under subparagraph (F) in a cost reporting period beginning on or after October 1, 2002, is equal to the sum of—

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A of this title, but subject to the provisions of section 1395e of this title, for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(A) In general

Notwithstanding section 1395f(b) of this title, but subject to the provisions of section 1395e of this title, the amount of the payment with respect to the operating and capital costs of inpatient hospital services of a rehabilitation facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, is equal to the sum of—

(i) the TEFRA percentage (as defined in subparagraph (C)) of the amount that would have been paid under part A of this title, and (ii) the prospective payment percentage (as defined in subparagraph (C)) of the product of (I) the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs, and (II) the number of such payment units occurring in the cost reporting period.

(C) TEFRA and prospective payment percentages specified

For purposes of subparagraph (A), for a cost reporting period beginning—
(i) on or after October 1, 2000, and before 
October 1, 2001, the “TEFRA percentage” is 66% percent and the “prospective payment percentage” is 33% percent; and
(ii) on or after October 1, 2001, and before 
October 1, 2002, the “TEFRA percentage” is 33% percent and the “prospective payment percentage” is 66% percent.

(D) Payment unit

For purposes of this subsection, the term “payment unit” means a discharge.

(E) Construction relating to transfer authority

Nothing in this subsection shall be construed as preventing the Secretary from providing for an adjustment to payments to take into account the early transfer of a patient from a rehabilitation facility to another site of care.

(F) Election to apply full prospective payment system

A rehabilitation facility may elect, not later than 30 days before its first cost reporting period for which the payment methodology under this subsection applies to the facility, to have payment made to the facility under this subsection under the provisions of subparagraph (B) (rather than subparagraph (A)) for each cost reporting period to which such payment methodology applies.

(2) Patient case mix groups

(A) Establishment

The Secretary shall establish—

(i) classes of patient discharges of rehabilitation facilities by functional-related groups (each in this subsection referred to as a “case mix group”), based on impairment, age, comorbidities, and functional capability of the patient and such other factors as the Secretary deems appropriate to improve the explanatory power of functional independence measure-function related groups; and

(ii) a method of classifying specific patients in rehabilitation facilities within these groups.

(B) Weighting factors

For each case mix group the Secretary shall assign an appropriate weighting which reflects the relative facility resources used with respect to patients classified within that group compared to patients classified within other groups.

(C) Adjustments for case mix

(i) In general

The Secretary shall from time to time adjust the classifications and weighting factors established under this paragraph as appropriate to reflect changes in treatment patterns, technology, case mix, number of payment units for which payment is made under this subchapter, and other factors which may affect the relative use of resources. Such adjustments shall be made in a manner so that changes in aggregate payments under the classification system are a result of real changes and are not a result of changes in coding that are unrelated to real changes in case mix.

(ii) Adjustment

Insofar as the Secretary determines that such adjustments for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under the classification system during the fiscal year that are a result of changes in the coding or classification of patients that do not reflect real changes in case mix, the Secretary shall adjust the per payment unit payment rate for subsequent years so as to eliminate the effect of such coding or classification changes.

(D) Data collection

The Secretary is authorized to require rehabilitation facilities that provide inpatient hospital services to submit such data as the Secretary deems necessary to establish and administer the prospective payment system under this subsection.

(3) Payment rate

(A) In general

The Secretary shall determine a prospective payment rate for each payment unit for which such rehabilitation facility is entitled to receive payment under this subchapter. Subject to subparagraph (B), such rate for payment units occurring during a fiscal year shall be based on the average payment per payment unit under this subchapter for inpatient operating and capital costs of rehabilitation facilities that provide inpatient care services to patients classified under paragraph (4) (relating to outpatient and related payments);

(i) by updating such per-payment-unit amount to the fiscal year involved by the weighted average of the applicable percentage increases provided under subsection (b)(3)(B)(ii) of this section (for cost reporting periods beginning during the fiscal year covering the period from the midpoint of the period for such data through the midpoint of fiscal year 2000); and by an increase factor (described in subparagraph (C)) specified by the Secretary for subsequent fiscal years up to the fiscal year involved;

(ii) by reducing such rates by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on prospective payment amounts which are additional payments described in paragraph (4) (relating to outlier and related payments);

(iii) for variations among rehabilitation facilities by area under paragraph (6);

(iv) by the weighting factors established under paragraph (2)(B); and

(v) by such other factors as the Secretary determines are necessary to properly reflect variations in necessary costs of treatment among rehabilitation facilities.
(B) Budget neutral rates

The Secretary shall establish the prospective payment amounts under this subsection for payment units during fiscal years 2001 and 2002 at levels such that, in the Secretary’s estimation, the amount of total payments under this subsection for such fiscal years (including any payment adjustments pursuant to paragraphs (4) and (6) but not taking into account any payment adjustment resulting from an election permitted under paragraph (1)(P)) shall be equal to 98 percent for fiscal year 2001 and 100 percent for fiscal year 2002 of the amount of payments that would have been made under this subchapter during the fiscal years for operating and capital costs of rehabilitation facilities had this subsection not been enacted. In establishing such payment amounts, the Secretary shall consider the effects of the prospective payment system established under this subsection on the total number of payment units from rehabilitation facilities and other factors described in subparagraph (A).

(C) Increase factor

(i) In general

For purposes of this subsection for payment units in each fiscal year (beginning with fiscal year 2001), the Secretary shall establish an increase factor subject to clause (ii). Such factor shall be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made under this subsection, which may be the market basket percentage increase described in subsection (b)(3)(B)(iii) of this section. The increase factor to be applied under this subparagraph for each of fiscal years 2008 and 2009 shall be 0 percent.

(ii) Productivity and other adjustment

After establishing the increase factor described in clause (i) for a fiscal year, the Secretary shall reduce such increase factor—

(I) for fiscal year 2012 and each subsequent fiscal year, by the productivity adjustment described in subsection (b)(3)(B)(i)(II); and

(II) for each of fiscal years 2010 through 2019, by the other adjustment described in subparagraph (D).

The application of this clause may result in the increase factor under this subparagraph being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(D) Other adjustment

For purposes of subparagraph (C)(i)(II), the other adjustment described in this subparagraph is—

(i) for each of fiscal years 2010 and 2011, 0.25 percentage point;

(ii) for each of fiscal years 2012 and 2013, 0.1 percentage point;

(iii) for fiscal year 2014, 0.3 percentage point;

(iv) for each of fiscal years 2015 and 2016, 0.2 percentage point; and

(v) for each of fiscal years 2017, 2018, and 2019, 0.75 percentage point.

(4) Outlier and special payments

(A) Outliers

(i) In general

The Secretary may provide for an additional payment to a rehabilitation facility for patients in a case mix group, based upon the patient being classified as an outlier based on an unusual length of stay, costs, or other factors specified by the Secretary.

(ii) Payment based on marginal cost of care

The amount of such additional payment under clause (i) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the cutoff point applicable under clause (i).

(iii) Total payments

The total amount of the additional payments made under this subparagraph for payment units in a fiscal year may not exceed 5 percent of the total payments projected or estimated to be made based on prospective payment rates for payment units in that year.

(B) Adjustment

The Secretary may provide for such adjustments to the payment amounts under this subsection as the Secretary deems appropriate to take into account the unique circumstances of rehabilitation facilities located in Alaska and Hawaii.

(5) Publication

The Secretary shall provide for publication in the Federal Register, on or before August 1 before each fiscal year (beginning with fiscal year 2001), of the classification and weighting factors for case mix groups under paragraph (2) for such fiscal year and a description of the methodology and data used in computing the prospective payment rates under this subsection for that fiscal year.

(6) Area wage adjustment

The Secretary shall adjust the proportion (as estimated by the Secretary from time to time) of rehabilitation facilities’ costs which are attributable to wages and wage-related costs, of the prospective payment rates computed under paragraph (3) for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. Not later than October 1, 2001 (and at least every 36 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of information available to the Secretary (and updated as appropriate) of the wages and wage-related costs incurred in furnishing rehabilitation services. Any adjustments or up-
dates made under this paragraph for a fiscal year shall be made in a manner that assures that the aggregated payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment.

(7) Quality reporting

(A) Reduction in update for failure to report

(i) In general

For purposes of fiscal year 2014 and each subsequent fiscal year, in the case of a rehabilitation facility that does not submit data to the Secretary in accordance with subparagraph (C) with respect to such a fiscal year, after determining the increase factor described in paragraph (3)(C), and after application of paragraph (3)(D), the Secretary shall reduce such increase factor for payments for discharges occurring during such fiscal year by 2 percentage points.

(ii) Special rule

The application of this subparagraph may result in the increase factor described in paragraph (3)(C) being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(B) Noncumulative application

Any reduction under subparagraph (A) shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the payment amount under this subsection for a subsequent fiscal year.

(C) Submission of quality data

For fiscal year 2014 and each subsequent rate year, each rehabilitation facility shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) 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) Time frame

Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to fiscal year 2014.

(E) Public availability of data submitted

The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a rehabilitation facility has the opportunity to review the data that is to be made public with respect to the facility prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in rehabilitation facilities on the Internet website of the Centers for Medicare & Medicaid Services.

(8) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of the establishment of—

(A) case mix groups, of the methodology for the classification of patients within such groups, and of the appropriate weighting factors thereof under paragraph (2),

(B) the prospective payment rates under paragraph (3),

(C) outlier and special payments under paragraph (4), and

(D) area wage adjustments under paragraph (6).

(k) Payment to nonhospital providers

(1) In general

For purposes of this section, the term "qualified nonhospital providers" means—

(A) a Federally qualified health center, as defined in section 1395x(aa)(4) of this title;

(B) a rural health clinic, as defined in section 1395x(aa)(2) of this title;

(C) Medicare+Choice organizations; and

(D) such other providers (other than hospitals) as the Secretary determines to be appropriate.

(i) Payment for nursing and allied health education for managed care enrollees

(1) In general

For portions of cost reporting periods beginning on or after October 1, 1997, the Secretary may establish rules for payment to qualified nonhospital providers for their direct costs of medical education, if those costs are incurred in the operation of an approved medical residency training program described in subsection (h) of this section. Such rules shall specify the amounts, form, and manner in which such payments will be made and the portion of such payments that will be made from each of the trust funds under this subchapter.

(2) Qualified nonhospital providers

For purposes of this subsection, the term "qualified nonhospital providers" means—

(A) a Federally 14 qualified health center, as defined in section 1395x(aa)(4) of this title;

(B) a rural health clinic, as defined in section 1395x(aa)(2) of this title;

(C) Medicare+Choice organizations; and

(D) such other providers (other than hospitals) as the Secretary determines to be appropriate.

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(2) Payment amount

The additional payment amount under this subsection for each hospital for portions of cost reporting periods occurring in a year shall be an amount specified by the Secretary in a manner consistent with the following:

(A) Determination of managed care enrollee payment ratio for graduate medical education payments

The Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection (h)(3)(D) of this section to total direct graduate medical education payments estimated for such portions of periods under subsection (h)(3) of this section.

(B) Application to fee-for-service nursing and allied health education payments

Such ratio shall be applied to the Secretary’s estimate of total payments for nursing and allied health education determined under section 1395x(v) of this title for portions of cost reporting periods occurring in the year to determine a total amount of additional payments for nursing and allied health education that shall be distributed to hospitals under this subsection for portions of cost reporting periods occurring in the year; except that in no case shall such total amount exceed $60,000,000 in any year.

(C) Application to hospital

The amount of payment under this subsection to a hospital for portions of cost reporting periods occurring in a year is equal to the total amount of payments determined under subparagraph (B) for the year multiplied by the ratio of—

(i) the product of (I) the Secretary’s estimate of the ratio of the amount of payments made under section 1395x(v) of this title to the hospital for nursing and allied health education activities for the hospital’s cost reporting period ending in the second preceding fiscal year, to the hospital’s total inpatient days for such period, and (II) the total number of inpatient days (as established by the Secretary) for such period which are attributable to services furnished to individuals who are enrolled under a risk sharing contract with an eligible organization under section 1395mm of this title and who are entitled to benefits under part A of this subchapter or who are enrolled with a Medicare+Choice organization under part C of this subchapter; to

(ii) the sum of the products determined under clause (i) for such cost reporting periods.

(m) Prospective payment for long-term care hospitals

(1) Reference to establishment and implementation of system

For provisions related to the establishment and implementation of a prospective payment system for payments under this subchapter for inpatient hospital services furnished by a long-term care hospital described in subsection (d)(1)(B)(iv), see section 123 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

(2) Update for rate year 2008

In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2008 for a hospital, the base rate for such discharges for the hospital shall be the same as the base rate for discharges for the hospital occurring during the rate year ending in 2007.

(3) Implementation for rate year 2010 and subsequent years

(A) In general

In implementing the system described in paragraph (1) for rate year 2010 and each subsequent rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, shall be reduced—

(i) for rate year 2012 and each subsequent rate year, by the productivity adjustment described in subsection (b)(3)(B)(xi)(II); and

(ii) for each of rate years 2010 through 2019, by the other adjustment described in paragraph (4).

(B) Special rule

The application of this paragraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(4) Other adjustment

For purposes of paragraph (3)(A)(ii), the other adjustment described in this paragraph is—

(A) for rate year 2010, 0.25 percentage point;

(B) for rate year 2011, 0.50 percentage point;

(C) for each of the rate years beginning in 2012 and 2013, 0.1 percentage point;

(D) for rate year 2014, 0.3 percentage point;

(E) for each of rate years 2015 and 2016, 0.2 percentage point; and

(F) for each of rate years 2017, 2018, and 2019, 0.75 percentage point.

(5) Quality reporting

(A) Reduction in update for failure to report

(i) In general

Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a long-term care hospital that does not submit data to the Secretary in accordance with subparagraph (C) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (3), shall be reduced by 2 percentage points.

(ii) Special rule

The application of this subparagraph may result in such annual update being
less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) Noncumulative application

Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) Submission of quality data

For rate year 2014 and each subsequent rate year, each long-term care hospital shall submit to the Secretary data on quality measures specified under subparagraph (D). Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph.

(D) 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) Time frame

Not later than October 1, 2012, the Secretary shall publish the measures selected under this subparagraph that will be applicable with respect to rate year 2014.

(E) Public availability of data submitted

The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a long-term care hospital has the opportunity to review the data that is to be made public with respect to the hospital prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in long-term care hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(n) Incentives for adoption and meaningful use of certified EHR technology

(1) In general

Subject to the succeeding provisions of this subsection, with respect to inpatient hospital services furnished by an eligible hospital during a payment year (as defined in paragraph (2)(G)), if the eligible hospital is a meaningful EHR user (as determined under paragraph (3)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this section, there also shall be paid to the eligible hospital, from the Federal Hospital Insurance Trust Fund established under section 1395f of this title, an amount equal to the applicable amount specified in paragraph (2)(A) for the hospital for such payment year.

(2) Payment amount

(A) In general

Subject to the succeeding subparagraphs of this paragraph, the applicable amount specified in this subparagraph for an eligible hospital for a payment year is equal to the product of the following:

(i) Initial amount

The sum of—

(I) the base amount specified in subparagraph (B); plus

(II) the discharge related amount specified in subparagraph (C) for a 12-month period selected by the Secretary with respect to such payment year.

(ii) Medicare share

The Medicare share as specified in subparagraph (D) for the eligible hospital for a period selected by the Secretary with respect to such payment year.

(iii) Transition factor

The transition factor specified in subparagraph (E) for the eligible hospital for the payment year.

(B) Base amount

The base amount specified in this subparagraph is $2,000,000.

(C) Discharge related amount

The discharge related amount specified in this subparagraph for a 12-month period selected by the Secretary shall be determined as the sum of the amount, estimated based upon total discharges for the eligible hospital (regardless of any source of payment) for the period, for each discharge up to the 23,000th discharge as follows:

(i) For the first through 1,149th discharge, $0.

(ii) For the 1,150th through the 23,000th discharge, $200.

(iii) For any discharge greater than the 23,000th, $0.

(D) Medicare share

The Medicare share specified under this subparagraph for an eligible hospital for a period selected by the Secretary for a payment year is equal to the fraction—

(i) the numerator of which is the sum (for such period and with respect to the eligible hospital) of—

(I) the estimated number of inpatient-bed-days (as established by the Secretary) which are attributable to individuals with respect to whom payment may be made under part A; and

(II) the estimated number of inpatient-bed-days (as so established) which are at-
(G) Payment year defined
(i) In general
For purposes of this subsection, the term “payment year” means a fiscal year beginning with fiscal year 2011.

(ii) First, second, etc. payment year
The term “first payment year” means, with respect to inpatient hospital services furnished by an eligible hospital, the first fiscal year for which an incentive payment is made for such services under this subsection. The terms “second payment year”, “third payment year”, and “fourth payment year” mean, with respect to an eligible hospital, each successive year immediately following the first payment year for that hospital.

(3) Meaningful EHR user
(A) In general
For purposes of paragraph (1), an eligible hospital shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (b)(3)(B)(ix), for an EHR reporting period for such hospital) if each of the following requirements are met:

(i) Meaningful use of certified EHR technology
The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the hospital is using certified EHR technology in a meaningful manner.

(ii) Information exchange
The eligible hospital demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period such certified EHR technology is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination.

(iii) Reporting on measures using EHR
Subject to subparagraph (B)(i) and using such certified EHR technology, the eligible hospital submits information for such period, in a form and manner specified by the Secretary, on such clinical quality measures and such other measures as selected by the Secretary under subparagraph (B)(i).

The Secretary shall seek to improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use selected under this paragraph.

(B) Reporting on measures
(i) Selection
The Secretary shall select measures for purposes of subparagraph (A)(iii) but only consistent with the following:
(I) The Secretary shall provide preference to clinical quality measures that have been selected for purposes of applying subsection (b)(3)(B)(viii) or that have been endorsed by the entity with a contract with the Secretary under section 1395aaa(a) of this title.

(II) Prior to any measure (other than a clinical quality measure that has been selected for purposes of applying subsection (b)(3)(B)(viii)) being selected under this subparagraph, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(ii) Limitations

The Secretary may not require the electronic reporting of information on clinical quality measures under subparagraph (A)(iii) unless the Secretary has the capacity to accept the information electronically, which may be on a pilot basis.

(iii) Coordination of reporting of information

In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under subsection (b)(3)(B)(viii).

(C) Demonstration of meaningful use of certified EHR technology and information exchange

(i) In general

An eligible hospital may satisfy the demonstration requirement of clauses (i) and (ii) of subparagraph (A) through means specified by the Secretary, which may include—

(I) an attestation;

(II) the submission of claims with appropriate coding (such as a code indicating that inpatient care was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and

(V) other means specified by the Secretary.

(ii) Use of part D data

Notwithstanding sections 1395w–115(d)(2)(B) and 1395w–115(f)(2) of this title, the Secretary may use data regarding drug claims submitted for purposes of section 1395w–115 of this title that are necessary for purposes of subparagraph (A).

(4) Application

(A) Limitations on review

There shall be no administrative or judicial review under section 1395f of this title, section 1395gg of this title, or otherwise, of—

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (b)(3)(B)(ix), including selection of periods under paragraph (2) for determining, and making estimates or using proxies of, discharges under paragraph (2)(C) and inpatient-bed-days, hospital charges, charity charges, and Medicare share under paragraph (2)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (3), including selection of measures under paragraph (3)(B), specification of the means of demonstrating meaningful EHR use under paragraph (3)(C), and the hardship exception under subsection (b)(3)(B)(ix)(I); and

(iii) the specification of EHR reporting periods under paragraph (6)(B) 15 and the selection of the form of payment under paragraph (2)(F).

(B) Posting on website

The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format, a list of the names of the eligible hospitals that are meaningful EHR users under this subsection or subsection (b)(3)(B)(ix) (and a list of the names of critical access hospitals to which paragraph (3) or (4) of section 1395f(i) of this title applies), and other relevant data as determined appropriate by the Secretary. The Secretary shall ensure that an eligible hospital (or critical access hospital) has the opportunity to review the other relevant data that are to be made public with respect to the hospital (or critical access hospital) prior to such data being made public.

(5) Certified EHR technology defined

The term “certified EHR technology” has the meaning given such term in section 1395aaa(a) of this title.

(6) Definitions

For purposes of this subsection:

(A) EHR reporting period

The term “EHR reporting period” means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(B) Eligible hospital

The term “eligible hospital” means a subsection (d) hospital.

(o) Hospital value-based purchasing program

(1) Establishment

(A) In general

Subject to the succeeding provisions of this subsection, the Secretary shall establish a hospital value-based purchasing program (in this subsection referred to as the “Program”) under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards under paragraph (3) for the performance period for such fiscal year (as established under paragraph (4)).

(B) Program to begin in fiscal year 2013

The Program shall apply to payments for discharges occurring on or after October 1, 2012.

15So in original. Probably should be “(6)(A)”.
(C) Applicability of Program to hospitals

(i) In general

For purposes of this subsection, subject to clause (ii), the term “hospital” means a subsection (d) hospital (as defined in subsection (d)(1)(B)).

(ii) Exclusions

The term “hospital” shall not include, with respect to a fiscal year, a hospital—

(I) that is subject to the payment reduction under subsection (b)(3)(B)(viii)(I) for such fiscal year;

(II) for which, during the performance period for such fiscal year, the Secretary has cited deficiencies that pose immediate jeopardy to the health or safety of patients;

(III) for which there are not a minimum number (as determined by the Secretary) of measures that apply to the hospital for the performance period for such fiscal year; or

(IV) for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for such fiscal year.

(iii) Independent analysis

For purposes of determining the minimum numbers under subclauses (III) and (IV) of clause (ii), the Secretary shall have conducted an independent analysis of what numbers are appropriate.

(iv) Exemption

In the case of a hospital that is paid under section 1395f(b)(3) of this title, the Secretary may exempt such hospital from the application of this subsection if the State which is paid under such section submits an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(2) Measures

(A) In general

The Secretary shall select measures, other than measures of readmissions, for purposes of the Program. Such measures shall be selected from the measures specified under subsection (b)(3)(B)(viii).

(B) Requirements

(i) For fiscal year 2013

For value-based incentive payments made with respect to discharges occurring during fiscal year 2013, the Secretary shall ensure the following:

(1) Conditions or procedures

Measures are selected under subparagraph (A) that cover at least the following 6 specific conditions or procedures:

(aa) Acute myocardial infarction (AMI).

(bb) Heart failure.

(cc) Pneumonia.

(dd) Surgeries, as measured by the Surgical Care Improvement Project (formerly referred to as “Surgical Infection Prevention” for discharges occurring before July 2006).

(11) Healthcare-associated infections, as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan) of the Department of Health and Human Services.

(ii) HCAHPS

Measures selected under subparagraph (A) shall be related to the Hospital Consumer Assessment of Healthcare Providers and Systems survey (HCAHPS).

(iii) Inclusion of efficiency measures

For value-based incentive payments made with respect to discharges occurring during fiscal year 2014 or a subsequent fiscal year, the Secretary shall ensure that measures selected under subparagraph (A) include efficiency measures, including measures of “Medicare spending per beneficiary”. Such measures shall be adjusted for factors such as age, sex, race, severity of illness, and other factors that the Secretary determines appropriate.

(C) Limitations

(i) Time requirement for prior reporting and notice

The Secretary may not select a measure under subparagraph (A) for use under the Program with respect to a performance period for a fiscal year (as established under paragraph (4)) unless such measure has been specified under subsection (b)(3)(B)(viii) and included on the Hospital Compare Internet website for at least 1 year prior to the beginning of such performance period.

(ii) Measure not applicable unless hospital furnishes services appropriate to the measure

A measure selected under subparagraph (A) shall not apply to a hospital if such hospital does not furnish services appropriate to such measure.

(D) Replacing measures

Subclause (VI) of subsection (b)(3)(B)(viii) shall apply to measures selected under subparagraph (A) in the same manner as such subclause applies to measures selected under such subsection.

(3) Performance standards

(A) Establishment

The Secretary shall establish performance standards with respect to measures selected under paragraph (2) for a performance period for a fiscal year (as established under paragraph (4)).

(B) Achievement and improvement

The performance standards established under subparagraph (A) shall include levels of achievement and improvement.
(C) Timing

The Secretary shall establish and announce the performance standards under subparagraph (A) not later than 60 days prior to the beginning of the performance period for the fiscal year involved.

(D) Considerations in establishing standards

In establishing performance standards with respect to measures under this paragraph, the Secretary shall take into account appropriate factors, such as—

(i) practical experience with the measures involved, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods;
(ii) historical performance standards;
(iii) improvement rates; and
(iv) the opportunity for continued improvement.

(4) Performance period

For purposes of the Program, the Secretary shall establish the performance period for a fiscal year. Such performance period shall begin and end prior to the beginning of such fiscal year.

(5) Hospital performance score

(A) In general

Subject to subparagraph (B), the Secretary shall develop a methodology for assessing the total performance of each hospital based on performance standards with respect to the measures selected under paragraph (2) for a performance period (as established under paragraph (4)). Using such methodology, the Secretary shall provide for an assessment (in this subsection referred to as the “hospital performance score”) for each hospital for each performance period.

(B) Application

(i) Appropriate distribution

The Secretary shall ensure that the application of the methodology developed under subparagraph (A) results in an appropriate distribution of value-based incentive payments under paragraph (6) among hospitals achieving different levels of hospital performance scores, with hospitals achieving the highest hospital performance scores receiving the largest value-based incentive payments.

(ii) Higher of achievement or improvement

The methodology developed under subparagraph (A) shall provide that the hospital performance score for each measure.

(iii) Weights

The methodology developed under subparagraph (A) shall provide for the assignment of weights for categories of measures as the Secretary determines appropriate.

(iv) No minimum performance standard

The Secretary shall not set a minimum performance standard in determining the hospital performance score for any hospital.

(v) Reflection of measures applicable to the hospital

The hospital performance score for a hospital shall reflect the measures that apply to the hospital.

(6) Calculation of value-based incentive payments

(A) In general

In the case of a hospital that the Secretary determines meets (or exceeds) the performance standards under paragraph (3) for the performance period for a fiscal year (as established under paragraph (4)), the Secretary shall increase the base operating DRG payment amount (as defined in paragraph (7)(D)), as determined after application of paragraph (7)(B)(i), for a hospital for each discharge occurring in such fiscal year by the value-based incentive payment amount.

(B) Value-based incentive payment amount

The value-based incentive payment amount for each discharge of a hospital in a fiscal year shall be equal to the product of—

(i) the base operating DRG payment amount (as defined in paragraph (7)(D)) for the discharge for the hospital for such fiscal year; and

(ii) the value-based incentive payment percentage specified under subparagraph (C) for the hospital for such fiscal year.

(C) Value-based incentive payment percentage

(i) In general

The Secretary shall specify a value-based incentive payment percentage for a hospital for a fiscal year.

(ii) Requirements

In specifying the value-based incentive payment percentage for each hospital for a fiscal year under clause (i), the Secretary shall ensure that—

(I) such percentage is based on the hospital performance score of the hospital under paragraph (5); and

(II) the total amount of value-based incentive payments under this paragraph to all hospitals in such fiscal year is equal to the total amount available for value-based incentive payments for such fiscal year under paragraph (7)(A), as estimated by the Secretary.

(7) Funding for value-based incentive payments

(A) Amount

The total amount available for value-based incentive payments under paragraph (6) for all hospitals for a fiscal year shall be equal to the total amount of reduced payments for all hospitals under subparagraph (B) for such fiscal year, as estimated by the Secretary.

(B) Adjustment to payments

(i) In general

The Secretary shall reduce the base operating DRG payment amount (as defined
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in subparagraph (D)) for a hospital for each discharge in a fiscal year (beginning with fiscal year 2013) by an amount equal to the applicable percent (as defined in subparagraph (C)) of the base operating DRG payment amount for the discharge for the hospital for such fiscal year. The Secretary shall make such reductions for all hospitals in the fiscal year involved, regardless of whether or not the hospital has been determined by the Secretary to have earned a value-based incentive payment under paragraph (6) for such fiscal year.

(ii) No effect on other payments

Payments described in items (aa) and (bb) of subparagraph (D)(1)(II) for a hospital shall be determined as if this subsection had not been enacted.

(C) Applicable percent defined

For purposes of subparagraph (B), the term “applicable percent” means—

(i) with respect to fiscal year 2013, 1.0 percent;

(ii) with respect to fiscal year 2014, 1.25 percent;

(iii) with respect to fiscal year 2015, 1.5 percent;

(iv) with respect to fiscal year 2016, 1.75 percent; and

(v) with respect to fiscal year 2017 and succeeding fiscal years, 2 percent.

(D) Base operating DRG payment amount defined

(i) In general

Except as provided in clause (ii), in this subsection, the term “base operating DRG payment amount” means, with respect to a hospital for a fiscal year—

(I) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (q)) for a discharge if this subsection did not apply; reduced by

(II) any portion of such payment amount that is attributable to—

(aa) payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d); and

(bb) such other payments under subsection (d) determined appropriate by the Secretary.

(ii) Special rules for certain hospitals

(I) Sole community hospitals and medicare-dependent, small rural hospitals

In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal year 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (1) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(II) Hospitals paid under section 1395f

In the case of a hospital that is paid under section 1395f(b)(3) of this title, the term “base operating DRG payment amount” means the payment amount under such section.

(8) Announcement of net result of adjustments

Under the Program, the Secretary shall, not later than 60 days prior to the fiscal year involved, inform each hospital of the adjustments to payments to the hospital for discharges occurring in such fiscal year under paragraphs (6) and (7)(B)(i).

(9) No effect in subsequent fiscal years

The value-based incentive payment under paragraph (6) and the payment reduction under paragraph (7)(B)(i) shall each apply only with respect to the fiscal year involved, and the Secretary shall not take into account such value-based incentive payment or payment reduction in making payments to a hospital under this section in a subsequent fiscal year.

(10) Public reporting

(A) Hospital specific information

(i) In general

The Secretary shall make information available to the public regarding the performance of individual hospitals under the Program, including—

(I) the performance of the hospital with respect to each measure that applies to the hospital;

(II) the performance of the hospital with respect to each condition or procedure; and

(III) the hospital performance score assessing the total performance of the hospital.

(ii) Opportunity to review and submit corrections

The Secretary shall ensure that a hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under clause (i) prior to such information being made public.

(iii) Website

Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(B) Aggregate information

The Secretary shall periodically post on the Hospital Compare Internet website aggregate information on the Program, including—

(i) the number of hospitals receiving value-based incentive payments under paragraph (6) and the range and total amount of such value-based incentive payments; and

(ii) the number of hospitals receiving less than the maximum value-based incentive payment available to the hospital for the fiscal year involved and the range and amount of such payments.

(11) Implementation

(A) Appeals

The Secretary shall establish a process by which hospitals may appeal the calculation
of a hospital’s performance assessment with respect to the performance standards established under paragraph (3)(A) and the hospital performance score under paragraph (5). The Secretary shall ensure that such process provides for resolution of such appeals in a timely manner.

(B) Limitation on review

Except as provided in subparagraph (A), there shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:

(i) The methodology used to determine the amount of the value-based incentive payment under paragraph (6) and the determination of such amount.

(ii) The determination of the amount of funding available for such value-based incentive payments under paragraph (7)(A) and the payment reduction under paragraph (7)(B)(i).

(iii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).

(iv) The measures specified under subsection (b)(3)(B)(viii) and the measures selected under paragraph (2).

(v) The methodology developed under paragraph (5) that is used to calculate hospital performance scores and the calculation of such scores.


(C) Consultation with small hospitals

The Secretary shall consult with small rural and urban hospitals on the application of the Program to such hospitals.

(12) Promulgation of regulations

The Secretary shall promulgate regulations to carry out the Program, including the selection of measures under paragraph (2), the methodology developed under paragraph (5) that is used to calculate hospital performance scores, and the methodology used to determine the amount of value-based incentive payments under paragraph (6).

(p) Adjustment to hospital payments for hospital acquired conditions

(1) In general

In order to provide an incentive for applicable hospitals to reduce hospital acquired conditions under this subchapter, with respect to discharges from an applicable hospital occurring during fiscal year 2015 or a subsequent fiscal year, the amount of payment under this section or section 1395f(b)(3) of this title, as applicable, for such discharges during the fiscal year shall be equal to 99 percent of the amount of payment that would otherwise apply to such discharges under this section or section 1395f(b)(3) of this title (determined after the application of subsections (o) and (q) and section 1395f(l)(4) but without regard to this subsection).

(2) Applicable hospitals

(A) In general

For purposes of this subsection, the term “applicable hospital” means a subsection (d) hospital that meets the criteria described in subparagraph (B).

(B) Criteria described

(i) In general

The criteria described in this subparagraph, with respect to a subsection (d) hospital, is that the subsection (d) hospital is in the top quartile of all subsection (d) hospitals, relative to the national average, of hospital acquired conditions during the applicable period, as determined by the Secretary.

(ii) Risk adjustment

In carrying out clause (i), the Secretary shall ensure that an applicable hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established under this subsection.

(3) Hospital acquired conditions

For purposes of this subsection, the term “hospital acquired condition” means a condition identified for purposes of subsection (d)(4)(D)(iv) and any other condition determined appropriate by the Secretary that an individual acquires during a stay in an applicable hospital, as determined by the Secretary.

(4) Applicable period

In this subsection, the term “applicable period” means, with respect to a fiscal year, a period specified by the Secretary.

(5) Reporting to hospitals

Prior to fiscal year 2015 and each subsequent fiscal year, the Secretary shall provide confidential reports to applicable hospitals with respect to hospital acquired conditions of the applicable hospital during the applicable period.

(6) Reporting hospital specific information

(A) In general

The Secretary shall make information available to the public regarding hospital acquired conditions of each applicable hospital.

(B) Opportunity to review and submit corrections

The Secretary shall ensure that an applicable hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) Website

Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.
(7) Limitations on review

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

(A) The criteria described in paragraph (2)(A).
(B) The specification of hospital acquired conditions under paragraph (3).
(C) The specification of the applicable period under paragraph (4).
(D) The provision of reports to applicable hospitals under paragraph (5) and the information made available to the public under paragraph (6).

(q) Hospital readmissions reduction program

(1) In general

With respect to payment for discharges from an applicable hospital (as defined in paragraph (5)(C)) occurring during a fiscal year beginning on or after October 1, 2012, in order to account for excess readmissions in the hospital, the Secretary shall make payments (in addition to the payments described in this subsection, the term ''base operating DRG payment amount'' means, with respect to a hospital for a fiscal year—

(A) the base operating DRG payment amount (as defined in paragraph (2)) for the discharge; and
(B) the adjustment factor (described in paragraph (3)(A)) for the hospital for the fiscal year.

(2) Base operating DRG payment amount defined

(A) In general

Except as provided in subparagraph (B), in this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year—

(i) the payment amount that would otherwise be made under subsection (d) (determined without regard to subsection (o)) for a discharge if this subsection did not apply; reduced by
(ii) any portion of such payment amount that is attributable to payments under paragraphs (5)(A), (5)(B), (5)(F), and (12) of subsection (d).

(B) Special rules for certain hospitals

(i) Sole community hospitals and medicare-dependent, small rural hospitals

In the case of a medicare-dependent, small rural hospital (with respect to discharges occurring during fiscal years 2012 and 2013) or a sole community hospital, in applying subparagraph (A)(i), the payment amount that would otherwise be made under subsection (d) shall be determined without regard to subparagraphs (I) and (L) of subsection (b)(3) and subparagraphs (D) and (G) of subsection (d)(5).

(ii) Hospitals paid under section 1395f of this title

In the case of a hospital that is paid under section 1395f(b)(3) of this title, the Secretary may exempt such hospitals provided that States paid under such section submit an annual report to the Secretary describing how a similar program in the State for a participating hospital or hospitals achieves or surpasses the measured results in terms of patient health outcomes and cost savings established herein with respect to this section.

(3) Adjustment factor

(A) In general

For purposes of paragraph (1), the adjustment factor under this paragraph for an applicable hospital for a fiscal year is equal to the greater of—

(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or
(ii) the floor adjustment factor specified in subparagraph (C).

(B) Ratio

The ratio described in this subparagraph for a hospital for an applicable period is equal to 1 minus the ratio of—

(i) the aggregate payments for excess readmissions (as defined in paragraph (4)(A)) with respect to an applicable hospital for the applicable period; and
(ii) the aggregate payments for all discharges (as defined in paragraph (4)(B)) with respect to such applicable hospital for such applicable period.

(C) Floor adjustment factor

For purposes of subparagraph (A), the floor adjustment factor specified in this subparagraph for—

(i) fiscal year 2013 is 0.99; (ii) fiscal year 2014 is 0.98; or
(iii) fiscal year 2015 and subsequent fiscal years is 0.97.

(4) Aggregate payments, excess readmission ratio defined

For purposes of this subsection:

(A) Aggregate payments for excess readmissions

The term "aggregate payments for excess readmissions" means, for a hospital for an applicable period, the sum, for applicable conditions (as defined in paragraph (5)(A)), of the product, for each applicable condition, of—

(i) the base operating DRG payment amount for such hospital for such applicable period for such condition; and
(ii) the number of admissions for such condition for such hospital for such applicable period; and
(iii) the excess readmissions ratio (as defined in subparagraph (C)) for such hospital for such applicable period minus 1.

(B) Aggregate payments for all discharges

The term "aggregate payments for all discharges" means, for a hospital for an applicable period, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such applicable period.
(C) Excess readmission ratio

(i) In general

Subject to clause (ii), the term “excess readmissions ratio” means, with respect to an applicable condition for a hospital for an applicable period, the ratio (but not less than 1.0) of—

(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to such applicable period; to

(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

(ii) Exclusion of certain readmissions

For purposes of clause (i), with respect to a hospital, excess readmissions shall not include readmissions for an applicable condition for which there are fewer than a minimum number (as determined by the Secretary) of discharges for such applicable condition for the applicable period and such hospital.

(5) Definitions

For purposes of this subsection:

(A) Applicable condition

The term “applicable condition” means, subject to subparagraph (B), a condition or procedures for which—

(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to such applicable period; to

(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

(B) Expansion of applicable conditions

Beginning with fiscal year 2015, the Secretary shall, to the extent practicable, expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) as of March 23, 2010, to the additional 4 conditions that have been identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures as determined appropriate by the Secretary. In expanding such applicable conditions, the Secretary shall seek the endorsement described in subparagraph (A)(ii)(I) but may apply such measures without such an endorsement 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 as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

(C) Applicable hospital

The term “applicable hospital” means a subsection (d) hospital or a hospital that is paid under section 1395f(b)(3) of this title, as the case may be.

(D) Applicable period

The term “applicable period” means, with respect to a fiscal year, such period as the Secretary shall specify.

(E) Readmission

The term “readmission” means, in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.

(6) Reporting hospital specific information

(A) In general

The Secretary shall make information available to the public regarding readmission rates of each subsection (d) hospital under the program.

(B) Opportunity to review and submit corrections

The Secretary shall ensure that a subsection (d) hospital has the opportunity to review, and submit corrections for, the information to be made public with respect to the hospital under subparagraph (A) prior to such information being made public.

(C) Website

Such information shall be posted on the Hospital Compare Internet website in an easily understandable format.

(7) Limitations on review

There shall be no administrative or judicial review under section 1395f of this title, section 1395oo of this title, or otherwise of the following:

(A) The determination of base operating DRG payment amounts.

(B) The methodology for determining the adjustment factor under paragraph (3), including excess readmissions ratio under paragraph (4)(C), aggregate payments for excess readmissions under paragraph (4)(A), and aggregate payments for all discharges under paragraph (4)(B), and applicable periods and applicable conditions under paragraph (5).

(C) The measures of readmissions as described in paragraph (5)(A)(ii).
(8) Readmission rates for all patients

(A) Calculation of readmission

The Secretary shall calculate readmission rates for all patients (as defined in subparagraph (D)) for a specified hospital (as defined in subparagraph (D)(ii)) for an applicable condition (as defined in paragraph (5)(B)) and other conditions deemed appropriate by the Secretary for an applicable period (as defined in paragraph (5)(D)) in the same manner as used to calculate such readmission rates for hospitals with respect to this subchapter and posted on the CMS Hospital Compare website.

(B) Posting of hospital specific all patient readmission rates

The Secretary shall make information on all patient readmission rates calculated under subparagraph (A) available on the CMS Hospital Compare website in a form and manner determined appropriate by the Secretary. The Secretary may also make other information determined appropriate by the Secretary available on such website.

(C) Hospital submission of all patient data

(i) Except as provided for in clause (ii), each specified hospital (as defined in subparagraph (D)(ii)) shall submit to the Secretary, in a form, manner and time specified by the Secretary, data and information determined necessary by the Secretary for the Secretary to calculate the all patient readmission rates described in subparagraph (A).

(ii) Instead of a specified hospital submitting to the Secretary the data and information described in clause (i), such data and information may be submitted to the Secretary, on behalf of such a specified hospital, by a state or an entity determined appropriate by the Secretary.

(D) Definitions

For purposes of this paragraph:

(i) The term “all patients” means patients who are treated on an inpatient basis and discharged from a specified hospital (as defined in clause (i)).

(ii) The term “specified hospital” means a subsection (d) hospital, hospitals described in clauses (i) through (v) of subparagraph (D)(1)(B) and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described in this subparagraph.

(r) Adjustments to medicare DSH payments

(1) Empirically justified DSH payments

For fiscal year 2014 and each subsequent fiscal year, instead of the amount of disproportionate share hospital payment that would otherwise be made under subsection (d)(5)(F) to a subsection (d) hospital for the fiscal year, the Secretary shall pay to the subsection (d) hospital 25 percent of such amount (which represents the empirically justified amount for such payment, as determined by the Medicare Payment Advisory Commission in its March 2007 Report to the Congress).

(2) Additional payment

In addition to the payment made to a subsection (d) hospital under paragraph (1), for fiscal year 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of the following factors:

(A) Factor one

A factor equal to the difference between—

(i) the aggregate amount of payments that would be made to subsection (d) hospitals under subsection (d)(5)(F) if this subsection did not apply for such fiscal year (as estimated by the Secretary); and

(ii) the aggregate amount of payments that are made to subsection (d) hospitals under paragraph (1) for such fiscal year (as so estimated).

(B) Factor two

(i) Fiscal years 2014, 2015, 2016, and 2017

For each of fiscal years 2014, 2015, 2016, and 2017, a factor equal to 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, as determined by comparing the percent of such individuals—

(I) who are uninsured in 2013, the last year before coverage expansion under the Patient Protection and Affordable Care Act (as calculated by the Secretary based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Health Care and Education Reconciliation Act of 2010 that, if determined in the affirmative, would clear such Act for enrollment); and

(II) who are uninsured in the most recent period for which data is available (as so calculated), minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017.

(ii) 2018 and subsequent years

For fiscal year 2018 and each subsequent fiscal year, a factor equal to 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals—

(I) who are uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of the Centers for Medicare & Medicaid Services); and

(II) who are uninsured in the most recent period for which data is available (as so estimated and certified), minus 0.2 percentage points for each of fiscal years 2018 and 2019.

(C) Factor three

A factor equal to the percent, for each subsection (d) hospital, that represents the quotient of—

(i) the amount of uncompensated care for such hospital for a period selected by
the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines that alternative data is available which is a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data); and
(ii) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under this subsection for such period (as so estimated, based on such data).

(3) Limitations on review
There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:
(A) Any estimate of the Secretary for purposes of determining the factors described in paragraph (2);
(B) Any period selected by the Secretary for purposes of determining the factors described in paragraph (2).

(s) Prospective payment for psychiatric hospitals
(1) Reference to establishment and implementation of system
For provisions related to the establishment and implementation of a prospective payment system for payments under this subchapter for inpatient hospital services furnished by psychiatric hospitals (as described in clause (i) of subsection (d)(1)(B)) and psychiatric units (as described in the matter following clause (v) of subsection (d)(1)(B)) and psychiatric units (as described in clause (v) of subsection (d)(1)(B)) and psychiatric units (as described in clause (v) of subsection (d)(1)(B)), see section 121 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(2) Implementation for rate year beginning in 2010 and subsequent rate years
(A) In general
In implementing the system described in paragraph (1) for the rate year beginning in 2010 and any subsequent rate year, any update to a base rate for days during the rate year for a psychiatric hospital or unit, respectively, shall be reduced—
(i) for the rate year beginning in 2012 and each subsequent rate year, by the productivity adjustment described in subsection (b)(4)(B)(xi)(II); and
(ii) for each of the rate years beginning in 2010 through 2019, by the other adjustment described in paragraph (3).

(B) Special rule
The application of this paragraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(2) Implementation for rate year beginning in 2010 and subsequent rate years
(A) In general
In implementing the system described in paragraph (1) for the rate year beginning in 2010 and any subsequent rate year, any update to a base rate for days during the rate year for a psychiatric hospital or unit, respectively, shall be reduced—
(i) for the rate year beginning in 2012 and each subsequent rate year, by the productivity adjustment described in subsection (b)(4)(B)(xi)(II); and
(ii) for each of the rate years beginning in 2010 through 2019, by the other adjustment described in paragraph (3).

(B) Special rule
The application of this paragraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(3) Other adjustment
For purposes of paragraph (2)(A)(ii), the other adjustment described in this paragraph is—
(A) for each of the rate years beginning in 2010 and 2011, 0.25 percentage point;
(B) for each of the rate years beginning in 2010 through 2019, 0.75 percentage point.

(4) Quality reporting
(A) Reduction in update for failure to report
(i) In general
Under the system described in paragraph (1), for rate year 2014 and each subsequent rate year, in the case of a psychiatric hospital or psychiatric unit that does not submit data to the Secretary in accordance with subparagraph (C) with respect to such a rate year, any annual update to a standard Federal rate for discharges for the hospital during the rate year, and after application of paragraph (2), shall be reduced by 2 percentage points.

(ii) Special rule
The application of this subparagraph may result in such annual update being less than 0.0 for a rate year, and may result in payment rates under the system described in paragraph (1) for a rate year being less than such payment rates for the preceding rate year.

(B) Noncumulative application
Any reduction under subparagraph (A) shall apply only with respect to the rate year involved and the Secretary shall not take into account such reduction in computing the payment amount under the system described in paragraph (1) for a subsequent rate year.

(C) Submission of quality data
For rate year 2014 and each subsequent rate year, each psychiatric hospital and psychiatric unit shall submit to the Secretary data on quality measures specified under subsection (d)(1)(B) with respect to such purposes.

(D) Quality measures
(i) In general
Subject to clause (ii), any measure specified by the Secretary for purposes of determining the factors described in paragraph (2) must have been endorsed by the Secretary for which a feasible and practical measure has not been endorsed by the Secretary for purposes of determining the factors described in paragraph (2).

(ii) Exception
In the case of a specified area or medical topic determined appropriate by the Secretary, any measure specified by the Secretary for purposes of determining the factors described in paragraph (2) must have been endorsed by the Secretary for purposes of determining the factors described in paragraph (2).

(iii) Time frame
Not later than October 1, 2012, the Secretary shall publish the measures selected
under this subparagraph that will be applicable with respect to rate year 2014.

(E) Public availability of data submitted

The Secretary shall establish procedures for making data submitted under subparagraph (C) available to the public. Such procedures shall ensure that a psychiatric hospital and a psychiatric unit has the opportunity to review the data that is to be made public with respect to the hospital or unit prior to such data being made public. The Secretary shall report quality measures that relate to services furnished in inpatient settings in psychiatric hospitals and psychiatric units on the Internet website of the Centers for Medicare & Medicaid Services.

Pub. L. 92–603, Oct. 30, 1972, referred to in subsec. (c)(4)(B), is section 222(a) of the Social Security Amendments of 1972, referred to in subsec. (c)(4)(B), is section 222(a) of the Social Security Amendments of 1972, which is set out as a note under section 1395b–1 of this title.
Section 910(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985, referred to in subsec. (d)(2)(C)(1), is section 910(a) of Pub. L. 99–272, which amended subsection (d)(2)(C)(ii) of this section.


Section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, referred to in subsec. (d)(2)(C)(i), is section 111 of Pub. L. 106–113, which amended this section and enacted provisions set out as a note under this section.

Section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, referred to in subsec. (d)(2)(C)(ii), is section 302 of Pub. L. 106–554, which amended this section and enacted provisions set out as a note under this section.

Section 6003(c) of the Omnibus Budget Reconciliation Act of 1989, referred to in subsec. (d)(2)(C)(iv), is section 6003(c) of Pub. L. 101–239, which amended this section and enacted provisions set out below.

Section 402(b) of the Omnibus Budget Reconciliation Act of 1990, referred to in subsec. (d)(2)(C)(iv), is section 402(b) of Pub. L. 101–508, which amended this section and enacted provisions set out below.

Section 393 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, referred to in subsec. (d)(2)(C)(iv), is section 393 of Pub. L. 101–508, which amended this section and enacted provisions set out below.

Section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985, referred to in subsec. (d)(3)(C)(i), is section 9104 of Pub. L. 99–272, which amended subsection (d)(2)(C)(i), (3)(C), (D)(i), (ii)(I), and (iii)(II) of this section.


Such section 332(a)(1)(A), referred to in subsec. (b)(3)(B)(ix)(I), probably means section 332(a)(1)(A) of the Public Health Service Act, which is classified to section 254a–1(a)(1) of this title.

Section 608(e) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (i), is section 608(e) of Pub. L. 100–203, which is set out below.


Section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, referred to in subsec. (m)(1), is section 307(b) of Pub. L. 106–554, which enacted provisions set out as a note under this section.


Section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, referred to in subsec. (s)(1), is section 1000(a)(6) of Pub. L. 106–113, which enacted provisions set out as a note under this section.

AMENDMENTS

2010—Subsec. (a)(4). Pub. L. 111–192, § 102(a)(1), inserted “in applying the first sentence of this paragraph, the term ‘other services related to the admission’ includes all services that are not diagnostic services (other than such services (other than ambulatory diagnostic services) for which payment may be made under this subchapter that are provided by a hospital (or an entity wholly owned or operated by the hospital) to a patient—“after ‘hemophilia,’ and added subpars. (A) and (B).

Subsec. (b)(3)(B)(ii)(XX). Pub. L. 111–148, § 3409(a)(1), substituted “clauses (viii), (ix), (x), and (xii)” for “clause (viii).”

Subsec. (b)(3)(B)(viii)(I). Pub. L. 111–148, § 3409(a)(2), inserted “of such applicable percentage increase (determined without regard to clause (ix), (x), or (xii))” after “one-quarter.”

Subsec. (b)(3)(B)(viii)(II). Pub. L. 111–148, § 3401(a)(2A), inserted at end “The Secretary may require hospitals to submit data on measures that are not used for the determination of value-based incentive payments under subsection (o).”


Subsec. (b)(3)(B)(ix)(I). Pub. L. 111–148, § 3409(a)(3), inserted “(determined without regard to clause (viii), (x), or (xii))” after “otherwise applicable under clause (I)”.


Subsec. (b)(3)(B)(xii)(II). Pub. L. 111–152, § 1109a(1)(A), placed subcl. (II), which was directed to be added by Pub. L. 111–148, § 10319(a)(3), after subcl. (I) and struck out “and” at end. See Amendment note below.


Subsec. (b)(3)(B)(xii)(III). Pub. L. 111–152, § 1109a(1)(B), added subcl. (III) and struck out former subcl. (III) which read “subject to clause (xii), for each of fiscal years 2014 through 2019, by 0.2 percentage point,”.

Pub. L. 111–148, § 10319(a)(2), (4), redesignated subcl. (II) as (III) and substituted “2014” for “2012.”


Subsec. (b)(3)(B)(xiii). Pub. L. 111–152, § 1105(a)(2), struck out cl. (xii) which read as follows: “Clause (xii) shall be applied with respect to any of fiscal years 2014 through 2019 by substituting ‘0.0 percentage points’ for ‘0.2 percentage point’,” if for such fiscal year—
Pub. L. 111–148, §5004(a), substituted “shall be counted and that—” for “shall be counted and that all the time,” inserted cl. (i) designation and “effective for cost reporting periods beginning before July 1, 2010, all the time;” before “so spent,” substituted “;” and “for” for “and” for period at end, added cl. (ii), and inserted concluding provisions.

Subsec. (h)(4)(F)(i). Pub. L. 111–148, §5003(a)(1), substituted “paragraphs (7) and (8)” for “paragraph (7)”.

Subsec. (h)(4)(H)(i). Pub. L. 111–148, §5006(a)(2), substituted “paragraphs (7) and (8)” for “paragraph (7)”.


Subsec. (k)(7)(E). Pub. L. 111–148, §5006(e), substituted “paragraph or paragraph (4)(H)(vi)” for “for paragraph or paragraph (8)”.

Pub. L. 111–148, §5003(a)(3), inserted “or paragraph (8)” before period at end.


Subsec. (j)(3)(C). Pub. L. 111–148, §5103(c)(3), which directed addition of subcl. (I) to (V) of former cl. (i) as cls. (i) to (v), respectively, and realigned margins.


Subsec. (j)(3)(D)(i)(II). Pub. L. 111–152, §1105(c)(3), struck out cl. (i) designation and heading, redesignated subcl. (I) to (V) of former cl. (i) as cls. (i) to (v), respectively, and realigned margins.

Pub. L. 111–152, §10301(c)(1), redesignated subcl. (I) as (III) and substituted “2014” for “2012”.


Subsec. (j)(3)(D)(ii). Pub. L. 111–152, §1105(c)(2), struck out cl. (ii). Text read as follows: “Clause (i)(II) shall be applied with respect to any of fiscal years 2014 through 2019 by substituting ‘0.0 percentage points’ for ‘0.2 percentage point,’ if for such fiscal year—

“(I) the excess (if any) of—

“(aa) the total percentage of the non-elderly insured population for the preceding fiscal year (based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Patient Protection and Affordable Care Act that, if determined in the affirmative, would clear such Act for enrollment); over

“(bb) the total percentage of the non-elderly insured population for such preceding fiscal year (as estimated by the Secretary); exceeds

“(II) 5 percentage points.”

Pub. L. 111–148, §3401(c)(2), (4), redesignated subcl. (I) as (III) and substituted “2014” for “2012”.


Subsec. (j)(3)(D)(iii). Pub. L. 111–148, §10301(c)(1)(B), added subcl. (III) and struck out former subcl. (III) which read as follows: “subject to clause (ii), for each of fiscal years 2014 through 2019, 0.2 percentage point. Such rules” for “Such rules” in introductory provisions.


Subsec. (m)(3). (4). Pub. L. 111–148, §3401(c), added pars. (3) and (4).

Subsec. (m)(3)(A). Pub. L. 111–148, §3004(b), added par. (7) and redesignated former par. (7) as (8).

Subsec. (m)(4)(A). Pub. L. 111–152, §1105(b)(3), struck out subpar. (A) designation and heading before “For purposes”, redesignated cl. (i) as subpar. (A), and realigned margin.

Subsec. (m)(4)(A)(ii), (iii). Pub. L. 111–152, §1105(b)(3), redesignated cls. (ii) and (iii) as subpars. (B) and (C), respectively, and realigned margins.

Pub. L. 111–148, §10319(b)(1), (C), added cls. (ii) and (iii). Former cl. (ii) redesignated (iv).

Subsec. (m)(4)(A)(iv). Pub. L. 111–152, §1105(b)(3), redesignated cl. (iv) as subpar. (D) and realigned margin.

Pub. L. 111–152, §1105(b)(1)(A), inserted cl. (iv) and struck out former cl. (iv), which read as follows: “subject to subparagraph (B), for each of rate years 2014 through 2016, 0.2 percentage point.”

Pub. L. 111–148, §10319(b)(1)(B), redesignated cl. (i) as (iv) and substituted “2014” for “2012”.

Subsec. (m)(4)(A)(v). Pub. L. 111–152, §1105(b)(3), redesignated cls. (v) and (vi) as subcls. (V) and (VI), respectively, and realigned margins.


Prior to amendment, text read as follows: “Subparagraph (A)(iv) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.0 percentage points’ for ‘0.2 percentage point’, if for such rate year—

‘‘(i) the excess (if any) of—

‘‘(I) the total percentage of the non-elderly insured population for the preceding rate year (based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Patient Protection and Affordable Care Act that, if determined in the affirmative, would clear such Act for enrollment); over

‘‘(II) the total percentage of the non-elderly insured population for such preceding rate year (as estimated by the Secretary); exceeds

‘‘(ii) 5 percentage points.’’

Subsec. (n). Pub. L. 111–148, §10309, redesignated “other than measures of readmissions,” after “shall select measures”.


Subsec. (q)(1). Pub. L. 111–148, §10309, in introductory provisions, substituted “the Secretary shall make payments in addition to the payments described in paragraph (2)(A)(i) for such a discharge to such hospital under subsection (d) or (section 1395ww(b)(3) of this title, as the case may be) in an amount equal to the product of—

‘‘(I) the excess (if any) of—

‘‘(i) the excess (if any) of—

‘‘(I) the excess (if any) of—

‘‘(i) the excess (if any) of—

‘‘(II) the total percentage of the non-elderly insured population for the preceding rate year (based on the most recent estimates available from the Director of the Congressional Budget Office before a vote in either House on the Patient Protection and Affordable Care Act that, if determined in the affirmative, would clear such Act for enrollment); over

‘‘(II) the total percentage of the non-elderly insured population for such preceding rate year (as estimated by the Secretary); exceeds

‘‘(ii) 5 percentage points.’’


Pub. L. 111–152, §1104(a)(1), substituted minus 0.1 percentage point” for “minus 1.5 percentage points”. in concluding provisions.


Subsec. (s)(3)(A)(i). Pub. L. 111–152, §1105(d)(1)(A), placed cl. (ii), which was directed to be added by Pub. L. 111–148, §10319(e)(3), after cl. (i) and struck out “and” at end. See Amendment note below.

Pub. L. 111–148, §10319(e)(3), which directed addition of cl. (i) (after clause (ii)”, could not be executed. See Amendment note above. Former cl. (i) redesignated (iii).

Subsec. (s)(3)(A)(ii). Pub. L. 111–152, §1105(d)(1)(B), added cl. (iii) and struck out former cl. (iii) which read as follows: “subject to subparagraph (B), for each of the rate years beginning in 2014 through 2016, 0.2 percentage point.”

Pub. L. 111–148, §10319(e)(3), (4), redesignated cl. (ii) as (iii) and substituted “2014” for “2012”.


Prior to amendment, text read as follows: “Subparagraph (A)(ii) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.6 percentage points’ for ‘0.2 percentage point’.


Prior to amendment, text read as follows: “Subparagraph (A)(ii) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.6 percentage points’ for ‘0.2 percentage point’.


Prior to amendment, text read as follows: “Subparagraph (A)(ii) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.6 percentage points’ for ‘0.2 percentage point’. in concluding provisions.


Prior to amendment, text read as follows: “Subparagraph (A)(ii) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.6 percentage points’ for ‘0.2 percentage point’.


Prior to amendment, text read as follows: “Subparagraph (A)(ii) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.6 percentage points’ for ‘0.2 percentage point’.


Prior to amendment, text read as follows: “Subparagraph (A)(ii) shall be applied with respect to any of rate years 2014 through 2016 by substituting ‘0.6 percentage points’ for ‘0.2 percentage point’.”


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tween cost and charges) or 75 percent of one standard deviation for the diagnosis-related group involved)” after “is inadequate”.


Subsec. (d)(7)(A). Pub. L. 108–173, § 406(b), inserted “or the determination of the applicable percentage increase under subparagraph (12)(A)(ii)” after “to subsection (b)(1) of this section”.


“(I) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area;

“(II) such rate for hospitals located in a rural area, for such discharges, adjusted in the manner provided in paragraph (3)(E) for different area wage levels. As used in this section, the term ‘subsection (d) Puerto Rico hospital’ means a hospital that is located in Puerto Rico and that would be a subsection (d) hospital (as defined in paragraph (1)(B)) if it were located in one of the fifty States.”


Subsec. (d)(9)(C)(ii). Pub. L. 108–173, § 401(c)(2)(B), inserted “(or for fiscal year 2004 and thereafter, the average standardized amount)” after “each of the average standardized amounts”.

Subsec. (d)(9)(C)(iii)(I). Pub. L. 108–173, § 401(c)(2)(C), struck out “for hospitals located in an urban or rural area, respectively” after “reduced under clause (ii))”.


Subsec. (h)(4)(H)(i). Pub. L. 108–173, § 422(a)(2), inserted “and subject to paragraph (7)” after “subparagraphs (F) and (G)”.


Pub. L. 106–554, § 1(a)(6) (title III, § 301(a)(2)(A)), which directed amendment of subcl. (XVII) by “striking ‘minus 1.1 percentage points’ and inserting ‘minus 0.55 percentage points’”, was executed as if an end quotation mark for the inserted material followed “points”, to reflect the probable intent of Congress.


Subsec. (b)(3)(I)(1). Pub. L. 106–554, § 1(a)(6) (title II, § 213(a)(1)), in introductory provisions, substituted “there shall be substituted for the amount otherwise determined under subsection (d)(4)(D)(i) of this section, if such substitution results in a greater amount of payment under this section for the hospital” for “that for its cost reporting period beginning during 1999 is paid on the basis of the target amount applicable to the hospital under subparagraph (C) and that elects (in a form and manner determined by the Secretary) this subparagraph to apply to the hospital, there shall be substituted for such target amount”.

Subsec. (b)(3)(I)(1)(D). Pub. L. 106–554, § 1(a)(6) (title II, § 213(a)(2)), substituted “the amount otherwise applicable to the hospital under subsection (d)(5)(D)(i) of this section (referred to in this clause as the ‘subsection (d)(5)(D)(i) amount’)” for “target amount otherwise applicable to the hospital under subparagraph (C) (referred to in this clause as the ‘paragraph (C) target amount’)”.


Subsec. (d)(1)(E). Pub. L. 106–554, § 1(a)(4) (div. B, title I, § 152(b)), substituted “For purposes of subclauses (II) and (III) of subparagraph (B)(v)” for “For purposes of subparagraph (B)(v)”.


often than once every 3 years the Secretary (through such survey or otherwise) shall measure'’ for ‘‘To the extent determined feasible by the Secretary, such survey or otherwise shall measure’’.

Subsec. (d)(4)(C)(i). Pub. L. 106–554, § 1(a)(6) [title V, § 533(b)(3)], substituted ‘‘technology (including a new medical service or technology under paragraph (5)(K))’’, for ‘‘technology’’.


Subsec. (b)(2)(A). Pub. L. 106–113, § 1000(a)(6) [title I, § 122(1)], substituted ‘‘Except as provided in subparagraph (E), in addition to’’ for ‘‘In addition to’’.


Subsec. (b)(3)(B)(i)(XVI) to (XVIII). Pub. L. 106–113, § 1000(a)(6) [title IV, § 406], added subcls. (XVI) and (XVII), redesignated former subcl. (XVII) as (XVIII), and struck out former subcl. (XVI) which read as follows: ‘‘For each of fiscal years 2001 and 2002, the market basket percentage increase minus 1.1 percentage point for hospitals in all areas, and’’.


Subsec. (b)(3)(C). Pub. L. 106–113, § 1000(a)(6) [title IV, § 406(1)], inserted ‘‘subject to subparagraph (I),’’ before ‘‘the term ‘target amount’ means’’ in introductory provisions.


Pub. L. 106–113, § 1000(a)(6) [title III, § 321(k)(15)(B)(ii)], substituted ‘‘and before October 1, 2001’’ for ‘‘and for cost reporting periods beginning on or after October 1, 1997, and before October 1, 2001, for’’ and for cost reporting periods beginning on or after October 1, 1997, and before October 1, 2001, for’’.


Pub. L. 106–113, § 1000(a)(6) [title I, § 122(1)], substituted ‘‘and for discharges beginning on or after October 1, 1997, and before October 1, 2001, for’’ and for cost reporting periods beginning on or after October 1, 1997, and before October 1, 2001, for’’.

Pub. L. 106–113, § 1000(a)(6) [title IV, § 406(2)(B)], substituted ‘‘‘for’’ and ‘‘of’’ for ‘‘and’’.

Pub. L. 106–113, § 1000(a)(6) [title IV, § 406(2)(B)], substituted ‘‘and before October 1, 2001’’ for ‘‘and before October 1, 2001, for’’.

Pub. L. 106–113, § 1000(a)(6) [title IV, § 406(2)(B)], substituted ‘‘and for discharges beginning on or after October 1, 1997, and before October 1, 2001, for’’ and for cost reporting periods beginning on or after October 1, 1997, and before October 1, 2001, for’’.
Subsec. (b)(7)(A)(i)(II). Pub. L. 106–113, §1000(a)(6) [title III, §321(h)], inserted “‘as estimated by the Secretary’” after “median”.

Subsec. (d)(2)(C). Pub. L. 106–113, §1000(a)(6) [title I, §111(c)], inserted “‘or any additional payments under such paragraph resulting from the application of section 111 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999’” after “‘Balanced Budget Act of 1997’”.


Subsec. (j)(2)(A)(i). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(2)], added cls. (i) and (ii) and concluding provisions and struck out former cls. (i) and (ii) and concluding provisions which read as follows: “‘(i) 50 percent of the amount by which the target amount exceeds the amount of the operating costs, or (ii) 5 percent of the target amount, whichever is less; or’.”


Subsec. (b)(3)(A). Pub. L. 105–33, §§4413(a)(1), 4416(2), in introductory provisions, substituted “subparagraph (C) and succeeding subparagraph,” for “subparagraphs (C), (D), and (E),” and inserted “and in paragraph (7)(A)(ii),” before “for purposes of this subsection”.

Subsec. (b)(3)(B)(i)(XIII) to (XVII). Pub. L. 105–33, §4401(a), added subcls. (XIII) to (XVII) which read as follows: “for fiscal year 1998 and each subsequent fiscal year, the market basket percentage increase for hospitals in all areas.”

Subsec. (b)(3)(B)(i)(VI) to (VII). Pub. L. 105–33, §4411(a)(1), added subcls. (VI) and (VII) and redesignated former subcl. (VI) as (VIII).


Subsec. (b)(3)(D). Pub. L. 105–33, §4204(a)(2)(A), substituted “September 30, 1994, and for cost reporting pe-
At end "In making such reductions, the Secretary shall treat the applicable update factor described in paragraph (3)(B)(vi) for a fiscal year as being equal to the market basket percentage for that year."

Subsec. (b)(4)(A)(i). Pub. L. 105–33, § 4419(a)(1), inserted at end "A hospital that was classified by the Secretary on or before September 30, 1995 (as defined in section 1395i–4(d) of this title)".


Subsec. (d)(1)(B). Pub. L. 105–33, § 4417(a)(1), inserted at end "A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) shall continue to be so classified notwithstanding that it is located in the same building as, or on the same campus as, another hospital.".


Subsec. (d)(1)(B)(vi). Pub. L. 105–33, § 4418(a)(1), designated existing provisions as subcl. (I), substituted "or" for semicolon at end, and added subcl. (II).


Subsec. (d)(2)(C)(i). Pub. L. 105–33, § 4421(a)(2), inserted at end "except that the Secretary shall not take into account any reduction in the amount of additional payments under paragraph (5)(B)(ii) resulting from the amendment made by section 4220(a)(1) of the Balanced Budget Act of 1997.".

Subsec. (d)(5)(A)(ii). Pub. L. 105–33, § 4466(c), substituted "(including existing provisions as subcl. (I), substituted "or" for semicolon at end, and added subcl. (II))".

Subsec. (d)(5)(A)(iv). Pub. L. 105–33, § 4466(c)(1), substituted "the first day of the 13-month period ending on September 30 of the preceding fiscal year." for "the first day of the preceding fiscal year.".

Subsec. (d)(10)(D)(iii). Pub. L. 105–33, § 4422(a), added cl. (iii) and redesignated former cl. (iii) as (iv).


Subsec. (e)(2). Pub. L. 105–33, § 4422(b)(1)(A)(i), struck out par. (2) which related to appointment, composition, and responsibilities of the Prospective Payment Assessment Commission.

Subsec. (e)(3). Pub. L. 105–33, § 4422(b)(1)(A)(ii), redesignated subpar. (B) as par. (3) and struck out subpar. (A) which read as follows: "The Commission, not later than the March 1 before the beginning of each fiscal year (beginning with fiscal year 1986), shall report its general recommendations to Congress on an appropriate change factor which should be used for inpatient hospital services for discharges in that fiscal year, together with its general recommendations under paragraph (2)(B) regarding the effectiveness and quality of health care delivery systems in the United States.".


Subsec. (e)(6). Pub. L. 105–33, § 4422(b)(1)(A)(i), struck out par. (6) which related to appointments, membership, responsibilities, compensation, access to records and information, audits, and appropriations concerning the Prospective Payment Assessment Commission.

Subsec. (g)(1)(A). Pub. L. 105–33, § 4402, inserted at end "In addition to the reduction described in the preceding sentence, for discharges occurring on or after October 1, 1997, the Secretary shall apply the budget neutrality adjustment factor used to determine the Federal capital payment rate in effect on September 30, 1995 (as described in section 412.352 of the Code of Federal Regulations), to (i) the unadjusted standard Federal capital payment rate (as described in section 412.398(c) of that title), substituted "as defined in section 1395i–4(d) of this title" for "as defined in section 1395i–4(g) of this title"").
fect on September 30, 1997, and, for discharges occurring on or after October 1, 1997, and before September 30, 2002, reduce the rates described in clauses (i) and (ii) by 1 percent.”


Subsec. (h)(4)(F) to (H). Pub. L. 105–33, § 4623, added subs. (F) to (H).

Subsec. (h)(5)(G). Pub. L. 105–33, § 4627(a), substituted “Subject to clauses (ii), (iii), and (iv)” for “Subject to clauses (ii) and (iii)” in cl. (i) and added cl. (iv).


1994—Subsec. (a)(4). Pub. L. 103–432, § 110(a), added “or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day” after “3 days”.

Subsec. (b)(3)(B)(iv)(II). Pub. L. 103–342, § 105(b), substituted “(to the extent the Secretary determines appropriate)” for “(except as payments under clause (i) are made)”.


Subsec. (b)(5)(E). Pub. L. 103–432, § 153(a), inserted “or any successor examination” after “Medical Sciences”.

Subsec. (b)(3)(B)(i)(X). Pub. L. 103–66, § 13501(a)(1)(B), substituted “percentage increase minus 2.5 percentage points for hospitals” for “percentage increase for hospitals” and struck out “and” at end.


Subsec. (b)(3)(B)(iii). Pub. L. 103–66, § 13501(a)(1)(D), struck out “and” at end of subcl. (iii), in subcl. (IV), substituted “for subsequent fiscal years” for “for subsequent fiscal year” and a comma for period at end, and added subs. (V) and (VI).


Subsec. (d)(1)(A)(i). Pub. L. 103–66, § 13501(f), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: “beginning on or after April 1, 1988, and ending on September 30, 1990, the sum of (I) 85 percent of the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, and (II) 15 percent of the regional adjusted DRG prospective payment rate determined under such paragraph.”

Subsec. (d)(5)(A)(i). Pub. L. 103–66, § 13501(c)(1), substituted “For discharges occurring during fiscal years ending on or before September 30, 1997, the Secretary” for “The Secretary”.

Subsec. (d)(5)(A)(ii). Pub. L. 103–66, § 13501(c)(2), substituted “or, for discharges in fiscal years beginning on or after October 1, 1994, exceed the applicable DRG prospective payment rate plus a fixed dollar amount determined by the Secretary,” for period at end.

Subsec. (d)(5)(A)(iii). Pub. L. 103–66, § 13501(c)(3), substituted “shall (except as payments under clause (i) are required to be reduced to take into account the requirements of clause (v) approximate)” for “shall approximate”.


Subsec. (d)(5)(B)(ii). Pub. L. 103–66, § 13506, inserted “or providing services at any entity receiving a grant under section 254c of this title that is under the ownership or control of the hospital (if the hospital incurs all, or substantially all, of the costs of the services furnished by such interns and residents)” after “the hospital”.

Subsec. (d)(5)(G)(i). Pub. L. 103–66, § 13501(c)(1)(A), which directed amendment of subsec. (d)(5)(G) in clause (i) in the matter preceding subclause (I), by striking “ending on or before March 31, 1993,” and all that fol-
laws and inserting “before October 1, 1994, in the case of a subsection (d) hospital which is a Medicare-dependent, small rural hospital, payment under paragraph (1(A) shall be equal to the sum of the amount determined under subsection (b)(3)(B)(i) and the amount determined under paragraph (1(A))” was executed by substituting the new language for “ending on or before October 1, 1994,” with respect to a subsection (d) hospital which is a Medicare-dependent, small rural hospital, payment under paragraph (1(A) shall be—

“(I) an amount based on 100 percent of the hospital’s target amount for the cost reporting period, as defined in section (b)(3)(D) of this section, or

“(II) the amount determined under paragraph (b)(3)(B) whichever results in the greater payment to the hospital,” to reflect the probable intent of Congress.


Subsec. (g)(1)(A). Pub. L. 103–66, § 13501(a)(3), struck out end “For discharges occurring after September 30, 1993, the Secretary shall reduce by 7.4 percent the unadjusted standard Federal capital payment rate (as defined in 42 CFR 410.38(c), as in effect on August 10, 1993) and shall (for hospital cost reporting periods beginning on or after October 1, 1993) redetermine which payment methodology is applied to the hospital under such system to take into account such reduction.”

Subsec. (h)(2)(D). Pub. L. 103–66, § 13563(a)(1), designated existing provisions as cl. (i), substituted “Except as provided in clause (ii), for each” for “For each”, and added cl. (ii).


Subsec. (h)(5)(F)(ii). Pub. L. 103–66, § 13563(b)(1)(B), inserted “or a preventive medicine residency or fellowship program” after “fellowship program”.

Subsec. (h)(5)(H)(i). Pub. L. 103–66, § 13563(a)(2), added subpar. (H) and redesignated former subpar. (H) as (i).

Subsec. (h)(5)(J). Pub. L. 103–66, § 13563(b)(1), added subpars. (H) and redesignated former subpar. (H) as (I).

1990—Subsec. (a)(4). Pub. L. 101–508, § 4003(a), struck out period at end of first sentence and inserted “,” and includes the costs of all services for which payment may be made under this subchapter that are provided by the hospital (or by an entity wholly owned or operated by the hospital) to the patient during the 3 days immediately preceding the date of the patient’s admission if such services are diagnostic services (including clinical diagnostic laboratory tests) or are other services related to the admission (as defined by the Secretary).”

Subsec. (b)(1)(B)(ii). Pub. L. 101–508, § 4005(a)(1), added cl. (ii) and struck out former cl. (ii) which read as follows: “in the case of cost reporting periods beginning on or after October 1, 1992, and before October 1, 1994, 25 percent of the amount by which the amount of the operating costs exceeds the target amount.”


Subsec. (b)(3)(B)(i)(VI). Pub. L. 101–508, § 4002(c)(1)(A), substituted “in a large urban or other urban area, and the market basket percentage increase minus 0.7 percentage point for hospitals located in a rural area” for “in all areas”.


Pub. L. 101–508, § 4002(a)(1)(B), substituted “in a large urban or other urban area, and the market basket percentage increase minus 0.6 percentage point for hospitals located in a rural area” for “in all areas”.


Subsec. (b)(3)(B)(i)(VIII). Pub. L. 101–508, § 4002(c)(1)(C), substituted “in a large urban or other urban area, and the market basket percentage increase minus 0.55 for hospitals located in a rural area,” for “in all areas,” and added subcl. (VIII).


Pub. L. 101–508, § 4002(c)(2)(A)(i), substituted “(A), (C), (D), and (E),” for “(A) and (E),” in introductory provisions.

Subsec. (b)(3)(C)(i)(II). Pub. L. 101–508, § 4002(c)(2)(A)(i), substituted “(A), (C), (D), and (E),” for “(A) and (E),” in introductory provisions.

Pub. L. 101–508, § 4005(c)(2), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (c)(4). Pub. L. 101–508, § 4008(c)(1), substituted “payments under the State system as compared to aggregate payments which would have been made under the national system since” for “rate of increase from” in last sentence.

Subsec. (d)(1)(A)(ii). Pub. L. 101–508, § 4002(e)(1), substituted “beginning on or after April 1, 1968, and ending on September 30, 1993,” for “beginning on or after October 1, 1987, is equal to the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges, or, if the average standardized amount (described in clause (i)(I) or clause (i)(I) of paragraph (3)(D) for hospitals within the region of, and in the same rural, large urban, or other urban area as, the hospital is greater than the average standardized amount (described in the respective clause) for hospitals within the United States in that type of area for discharges occurring during the period beginning on April 1, 1988, and ending on October 20, 1990,”.


Pub. L. 101–508, § 4002(b)(4)(A), struck out period at end and inserted “, except that the Secretary shall not exclude additional payments under such paragraph made as a result of the enactment of section 6003(c) of the Omnibus Budget Reconciliation Act of 1989,”.


Subsec. (d)(3)(B). Pub. L. 101–508, § 4002(c)(2)(B)(iii), substituted “by a factor equal to the proportion of payments under this subsection (as estimated by the Secretary) based on DRG prospective payment amounts which are additional payments described in paragraph
(5)(A) (relating to outlier payments),” for “for hospitals located in an urban area and for hospitals located in a rural area by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment amounts which are additional payments described in paragraph (5)(A) (relating to outlier payments) for hospitals located in such respective area.”

Subsec. (d)(3)(C)(ii). Pub. L. 101–508, § 4002(b)(3)(B)(B), substituted “occurring on or after October 1, 1986,” through the end of cl. (ii) for “occurring—” and subcls. (I) and (II) which read as follows:

“(I) on or after October 1, 1986, and before October 1, 1996, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) that would have resulted from the enactment of the amendments made by section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (ii)(II) of paragraph (5)(B) were applied for discharges occurring on or after October 1, 1986, in a large urban area or other urban area;”

“(II) on or after October 1, 1996, of an amount equal to the estimated reduction in the payment amounts under paragraph (5)(B) for those discharges that has resulted from the enactment of the amendments made by section 9104 of the Medicare and Medicaid Budget Reconciliation Amendments of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987 if the factor described in clause (ii)(II) of that paragraph, and

“the wage index for that urban area or an area, or for discharges occurring on or after April 1, 1986, in a large urban area or other urban area’’ to reflect the probable intent of Congress.”

Subsec. (d)(3)(D)(i). Pub. L. 101–508, § 4002(c)(2)(B)(iv)(I), which directed amendment of cl. (i) by substituting “a large urban area” for “an urban area,” and all that follows through “area,” was executed by making the substitution for “an urban area” (or, for discharges occurring on or after April 1, 1986, in a large urban area or other urban area)” to reflect the probable intent of Congress.

Subsec. (d)(3)(D)(ii). Pub. L. 101–508, § 4002(c)(2)(B)(v), struck out subpar. (D) which read as follows: “The Commission (established under subsection (e)(2) of this section) shall consult with and make recommendations to the Secretary with respect to the need for adjustments under subparagraph (C), based upon its evaluation of scientific evidence with respect to new practices of new technologies and treatment modalities. The Commission shall report to the Congress with respect to its evaluation of any adjustments made by the Secretary under subparagraph (C).”


“(I) on or after May 1, 1986, and before October 1, 1995, is equal to 1.89×((1+y)−0.05)−1, or

“(II) on or after October 1, 1995, is equal to 1.42×((1+y)−0.05)−1,”

where ‘r’ is the ratio of the hospital’s full-time equivalent interns and residents to beds.

Subsec. (d)(5)(D)(i). Pub. L. 101–508, § 4008(m)(2)(A), substituted “For purposes of this subchapter, the term” for “The term” at beginning.


Subsec. (d)(5)(F)(vii)(II). Pub. L. 101–508, § 4002(b)(1)(B), substituted “hospital—” and subdvs. (a) to (c) for “hospital, (P–15,6)+2.5,”.

Subsec. (d)(8)(C)(i). Pub. L. 101–508, § 4002(h)(1)(A)(ii), substituted “area, or by treating hospitals located in one urban area as being located in another urban area—” for “area—”.

Subsec. (d)(8)(C)(ii). Pub. L. 101–508, § 4002(h)(1)(A)(ii), amended subcl. (I) generally. Prior to amendment, subcl. (I) read as follows: “The Commission shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so reclassified) and to hospitals located in the counties so reclassified (as if each affected rural county were a separate urban area).”

Subsec. (d)(8)(C)(ii) to (iv). Pub. L. 101–508, § 4002(h)(1)(A)(iii), (iv), redesignated cls. (ii) and (iv) as (i) and (iii), respectively, and struck out former cl. (ii) which read as follows: “If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), by reclassifying a county from a rural to an urban area or by reclassifying an urban county from one urban area to another urban area—”

“(I) reduces the wage index for the urban area within which the county or counties is reclassified by 1 percentage point or less (as applied under this subsection), the Secretary in calculating such wage index under this subsection, shall exclude those counties so reclassified, or

“(II) reduces the wage index for the urban area within which the county or counties is reclassified by more than 1 percentage point (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so reclassified) and to hospitals located in the counties so reclassified (as if each affected county were a separate area).”

Subsec. (d)(8)(D). Pub. L. 101–508, § 4002(c)(2)(B)(v), struck out “for hospitals located in an urban area” after “determined under paragraph (3)” and struck out at end “The Secretary shall make such adjustment in payments under this section to hospitals located in rural areas as are necessary to assure that the aggregate payment to rural hospitals not affected by subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10) are not changed as a result of the application of subparagraphs (B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10).”


Subsec. (d)(10)(B)(ii). Pub. L. 101–508, § 4002(b)(2)(B)(ii), substituted “representative” for “representatives” and struck out “1 member shall be a member of the Propective Payment Assessment Commission, and at least” after “At least:”.


Subsec. (d)(10)(C)(iii)(I). Pub. L. 101–508, § 4002(h)(2)(B)(iv), substituted “Appeal of decisions of the Board shall be subject to the provisions of section 557b of title 5” for “A decision of the Board shall be final unless the unsuccessful applicant appeals such decision to the Secretary by not later than 15 days after the Board renders its decision. The Secretary in considering the appeal of an applicant shall receive no evidence but shall consider the record as a whole as such record appeared before the Board” and substituted “after the date on which” for “after”.

Subsec. (e)(2). Pub. L. 101–508, § 4002(g)(1), designated existing provisions as subpar. (A) and added subpars. (B) and (C).

Subsec. (e)(2)(A). Pub. L. 101–508, § 4002(g)(2)(B), substituted “The Commission” for “In addition to carrying out its functions under subsection (d)(4)(D) of this section, the Commission”.

Subsec. (e)(3)(A). Pub. L. 101–508, § 4002(g)(2)(C), substituted “Congress” for “the Secretary” and inserted
before period at end ‘‘, together with its general recommendations under paragraph (2)(B) regarding the effectiveness and quality of health care delivery systems in the United States’’.

Subsec. (e)(4). Pub. L. 101–108, § 4002(g)(2)(D), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (e)(5). Pub. L. 101–108, § 4002(g)(2)(E), substituted ‘‘recommendations’’ for ‘‘recommendation’’ in subpars. (A) and (B) and inserted at end ‘‘To the extent that the Secretary’s recommendations under paragraph (4) differ from the Commission’s recommendations for that fiscal year, the Secretary shall include in the publication referred to in subparagraph (A) an explanation of the Secretary’s grounds for not following the Commission’s recommendations’’.

Subsec. (e)(6)(G). Pub. L. 101–108, § 4002(g)(2)(F), redesignated cl. (ii) and (iii) as (i) and (ii), respectively, and struck out former cl. (i) which read as follows: ‘‘The Office shall report annually to the Congress on the functioning and progress of the Commission and on the status of the assessment of medical procedures and services by the Commission.’’

Subsec. (g)(1)(A). Pub. L. 101–108, § 4001(b), inserted at end ‘‘Aggregate payments made under subsection (d) of this section and this subsection during fiscal years 1992 through 1995 shall be reduced in a manner that results in a reduction (as estimated by the Secretary) in the amount of such payments equal to a 10 percent reduction in the amount of payments attributable to capital-related costs that would otherwise have been made during such fiscal year had the amount of such payments been based on reasonable costs (as defined in section 1395x(v) of this title)’’.


Subsec. (g)(3)(B). Pub. L. 101–108, § 4001(c), substituted ‘‘subparagraph (d)(5)(D)(iii) of this section or a rural primary care hospital (as defined in section 1395x(mm)(1) of this title)’’ for ‘‘subparagraph (d)(5)(D)(iii) of this section’’.

1989—Subsec. (a)(4). Pub. L. 101–239, § 6011(a), struck out ‘‘or’’ after ‘‘equity capital,’’ and substituted ‘‘October 1, 1987’’, or costs with respect to administering blood clotting factors to individuals with hemophilia for ‘‘October 1, 1987’’.

Subsec. (b)(3)(A). Pub. L. 101–239, § 6004(b)(1)(A), substituted ‘‘(C), (D), and (E)’’ for ‘‘(C) and (D)’’ in introductory provisions.

Pub. L. 101–239, § 6003(f)(2)(i), substituted ‘‘subparagraph (C) and (D)’’ for ‘‘paragraph (C)’’ in introductory provisions.

Pub. L. 101–239, § 6003(e)(1)(B)(i), substituted ‘‘(A) Excluding hospitals provided in subparagraph (C), for purposes of this subsection for ‘‘(A) For purposes of this subsection for ‘‘in introductory provisions.’’

Subsec. (b)(3)(B)(iv)(V). Pub. L. 101–239, § 6002(b)(1)(B), substituted ‘‘For purposes of subparagraphs (A) and (E) for ‘‘For purposes of subparagraphs (A) and (D)’’ in introductory provisions.


Subsec. (b)(4)(A). Pub. L. 101–239, § 6015(a), substituted ‘‘deems appropriate, including the assignment of a new base period which is more representative, as determined by the Secretary, of the reasonable and necessary cost of inpatient services and’’ for ‘‘deems appropriate, including the assignment of a new’’.

Subsec. (c)(4). Pub. L. 101–239, § 6022, substituted ‘‘the aggregate of increase from October 1, 1981, to the most recent date for which annual data are available’’ for ‘‘the aggregate payment or payments per inpatient admission or discharge during the three cost reporting periods beginning on or after October 1, 1983, after which such test, at the option of the Secretary, shall no longer apply, and such State systems shall be treated in the same manner as under other waivers’’ in second sentence.


Subsec. (d)(3)(E). Pub. L. 101–239, § 6003(b)(6), substituted ‘‘October 1, 1990, and October 1, 1993 (and at least every 36 months thereafter)’’ for ‘‘October 1, 1990 (and at least every 36 months thereafter)’’ and inserted at end ‘‘Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment.’’

Subsec. (d)(4)(C). Pub. L. 101–239, § 6003(b), designated existing provisions as cl. (i) and added clss. (ii) to (iv).

Subsec. (d)(5)(C). Pub. L. 101–239, § 6003(e)(1)(A)(i), (ii), (iv), (2)(B), redesignated former cl. (ii) as cl. (i), redesignated former cl. (i)(II) as cl. (ii) and substituted ‘‘clause (i)’’ for ‘‘subclause (I)’’ in three places, and redesignated former clss. (iii), (iv) and (iv) as subpars. (D), (E), (i), and (H), respectively.

Subsec. (d)(5)(D). Pub. L. 101–239, § 6003(e)(1)(A)(iv), amended former subpar. (C)(ii) generally, redesignating it as subpar. (D) and substituting clss. (i) to (iv) relating to payments to sole community hospitals for cost reporting periods beginning on or after Apr. 1, 1990, for former single paragraph relating to payments to such hospitals for cost reporting periods beginning on or after Oct. 1, 1984.


Subsec. (d)(5)(F)(iv)(I). Pub. L. 101–239, § 6003(c)(1)(A), substituted ‘‘the applicable formula described in clause (vii)’’ for ‘‘following formula: (P−10)(5.5)+2.5, where ‘‘P’’ is the hospital’s disproportionate patient percentage (as defined in clause (vii))’’.

Subsec. (d)(5)(F)(iv)(III). Pub. L. 101–239, § 6003(c)(2)(A)(ii), inserted ‘‘in subclause (IV) or (V) or’’ after ‘‘described’’.


Subsec. (d)(5)(F)(v)(II) to (IV). Pub. L. 101–239, § 6003(c)(2)(B), added subcl. (II), redesignated former subcls. (II) and (III) as (III) and (IV), respectively, and substituted ‘‘area and is not described in subclause (II) for ‘‘area’’ in subcl. (IV).’’


Subsec. (d)(5)(I). Pub. L. 101–239, § 6004(a)(2), struck out ‘‘(including exceptions and adjustments that may be appropriate with respect to hospitals involved extensively in treatment for and research on cancer)’’ after ‘‘deems appropriate’’.


Subsec. (d)(5)(C). Pub. L. 101–239, § 6003(b)(3), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: ‘‘(i) If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), (sic) by treating hospitals located in a rural county or counties
as being located in an urban area, reduces the wage index for that urban area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection separately to hospitals located in such urban area (excluding all the hospitals so treated) and to the hospitals so treated (as if each affected rural county were a separate urban area).

If the application of subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10), (sic) by treating hospitals located in such urban area (excluding all the hospitals located in other urban areas) as being located in an urban area, reduces the wage index for that urban area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for such rural area.

(i) Clause (i) shall only apply to discharges occurring on or after October 1, 1989, and before October 1, 1993.


Subsec. (d)(9)(B)(ii)(IV). Pub. L. 101–239, § 6003(h)(2)(B), substituted “(B) and (C) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10),” for “(B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10),”, (sic) by treating hospitals located in a rural county or counties as not being located in the rural area in a State, reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated (as if they were located in the rural area) had not been excluded from calculation of the wage index for that rural area.

Subsec. (d)(3)(A). Pub. L. 100–380, § 611(b)(1)(D), substituted “the publications described in subsection (e)(5) of this section” for “the publication described in subsection (e)(5)(B) of this section” in second sentence.


Subsec. (d)(8)(B). Pub. L. 100–360, § 611(b)(4)(A)(ii), substituted “for purposes of this subsection, the Secretary” for “the Secretary”.

Subsec. (d)(8)(B). Pub. L. 100–360, § 611(b)(4)(A)(ii), substituted “the rural county would otherwise be considered part of an urban area, under the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) published in the Federal Register on January 3, 1980, if the commuting rates used in determining outlying counties (or for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas),” for “—

(i) the rural county would otherwise be considered part of an urban area by the standards for designating Metropolitan Statistical Areas (and for designating New England County Metropolitan Areas) published in the Federal Register on January 3, 1980, if the commuting rates used in determining outlying counties (or for New England, similar recognized areas) were determined on the basis of the aggregate number of resident workers who commute to (and, if applicable under the standards, from) the central county or counties of all contiguous Metropolitan Statistical Areas (or New England County Metropolitan Areas),” for “—

(ii) either (I) the number of residents of the rural county who commute for employment to the central
Subsec. (d)(3). Pub. L. 100–203, §4002(c)(1)(A), substituted “large urban, other urban, or rural areas” for “urban or rural areas” in second sentence.

Subsec. (d)(3)(A)(i). Pub. L. 100–203, §4002(c)(1)(B), (C), as amended by Pub. L. 100–360, §411(b)(1)(E)(ii), designated existing provisions as cl. (i), substituted “For discharges occurring [sic] in a fiscal year beginning before October 1, 1987,” for “the Secretary” for “The Secretary” and “the fiscal year involved” for “each of fiscal years 1985, 1986, 1987, and 1988”, struck out “, and adjusted for subsequent fiscal years in accordance with the final determination of the Secretary under subsection (e)(4) of this section, and adjusted to reflect the most recent case-mix data available”, and added cls. (ii) and (iii).


Subsec. (d)(3)(D). Pub. L. 100–203, §4002(c)(1)(D)(i), substituted “hospitals in different areas” for “urban and rural hospitals” in heading.

Subsec. (d)(3)(D)(i). Pub. L. 100–203, §4002(c)(1)(D)(i), (ii), inserted “(or, for discharges occurring on or after April 1, 1988, in a large urban area or other urban area)” after first reference to “urban area”, and in subcl. (i) inserted “such” before “an urban area”.

Subsec. (d)(3)(E). Pub. L. 100–203, §4004(a)(1), formerly §4004(a), as redesignated by Pub. L. 100–360, §411(b)(5), inserted at end “Not later than October 1, 1990 (and at least every 36 months thereafter), the Secretary shall update the factor under the preceding sentence on the basis of a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States. To the extent determined feasible by the Secretary, such survey shall measure the earnings and paid hours of employment by occupational category and shall exclude data with respect to the wages and wage-related costs incurred in furnishing skilled nursing facility services.”


Pub. L. 100–203, §4003(a)(1), substituted “1989” for “1987” in subcls. (i) and (ii).


Subsec. (d)(5)(C)(ii). Pub. L. 100–203, §4009(c)(1), substituted “1990” for “1988” in second sentence and inserted after second sentence “A subsection (d) hospital that meets the criteria for classification as a sole community hospital and otherwise qualifies for the adjustment authorized by the preceding sentence may qualify for such an adjustment without regard to the formula by which payments are determined for the hospital under paragraph (1)(A)”.


Subsec. (d)(5)(F)(ii). Pub. L. 100–203, §4009(j)(3)(A), substituted “such net inpatient care revenues” for “such adjusted patient care revenues” for second reference to “such revenues”.


Subsec. (d)(5)(F)(iv). Pub. L. 100–203, §4009(b)(1), substituted “clause (v)” for “subclause (III)”. Pub. L. 100–203, §4003(b)(2), struck out “the lesser of 15 percent, or after “is equal to”.


Subsec. (d)(8). Pub. L. 100–203, §4003(a)(1), as amended by Pub. L. 100–360, §411(b)(1)(A), designated former provisions as subpar. (A), redesignated former subpar. (A) and clss. (i) and (ii) as cl. (i) and subcls. (i) and (ii),
respectively, redesignated former subpar. (B) and clus. (i) and (ii) as cl. (ii) and subcl. (I) and (II), respectively, and added subpars. (B) and (C).

Subsec. (d)(9)(A)(ii). Pub. L. 100–203, § 4002(c)(2), substituted “a large urban area,” for “an urban area, and” in subcl. (I), added subcl. (II), and redesignated former subcl. (II) as (III).

Subsec. (g)(3)(B). Pub. L. 100–203–§ 4006(b)(1)(B), struck out “or determine” after “recommend”.

Subsec. (e)(4). Pub. L. 100–203–§ 4002(f)(1)(C), substituted “for each fiscal year (beginning with fiscal year 1988)” for “for fiscal year 1988”, struck out “and” shall determine for each subsequent fiscal year the percentage change which will apply for purposes of this section as the applicable percentage increase (otherwise described in subsection (b)(3)(B) of this section) for discharges in that fiscal year, and,” after “in that fiscal year,” and amended last sentence generally. Prior to amendment, last sentence read as follows: “The percentage change shall be the same for all subsection (d) hospitals and subsection (d) Puerto Rico hospitals, but may be different from that for other hospitals (and units not included as such hospitals) and may vary among such other hospitals and units.”


Subsec. (e)(6)(B). Pub. L. 100–203–§ 4009(d)(1), as amended by Pub. L. 100–369, § 411(b)(8)(B), substituted “include individuals with national recognition for their expertise in health economics, hospital reimbursement, hospital financial management, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives” for “provide expertise and experience in the provision and financing of health care,” and struck last sentence which required Director to seek nominations from wide range of groups, including specified types of national organizations.

Subsec. (e)(6)(D). Pub. L. 100–203–§ 4003(b)(1), inserted at end “For purposes of pay (other than pay of members of the Commission) and employment benefits, rights and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate.”


Subsec. (f)(3). Pub. L. 100–93 amended par. (3) generally. Prior to amendment, par. (3) read as follows: “The provisions of paragraphs (2), (3), and (4) of section 1395y(d) of this title shall apply to determinations under paragraph (2) of this subsection in the same manner as they apply to determinations made under section 1395y(d)(1) of this title.”

Subsec. (g)(1). Pub. L. 100–203–§ 4006(b)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: “If the Congress does not enact legislation after April 20, 1983, and before October 1, 1987, respecting the payment under this subchapter for capital-related costs for inpatient hospital services, no payment may be made under this subchapter for capital-related costs of capital expenditures (as defined in section 1395x(v)(1) of this title), and for purposes of this section as the applicable percentage increase (other than the reasonable cost methodology described in section 1395xx(v)(1) of this title with respect to capital-related costs of any hospital that is such a sole community hospital for cost reporting periods beginning before October 1, 1990, and “(ii) in the design of such payment system that the aggregate payment amounts under this subchapter for such other capital-related costs for payments attributable to portions of cost reporting periods occurring during fiscal year 1988 and fiscal year 1989 shall approximate the aggregate payment amount under this subchapter that would have been made (taking into account the provisions of subparagraphs (A) and (B)) during that fiscal year but for the inclusion of such costs by the Secretary”.

Subsec. (h)(4)(C). Pub. L. 100–203–§ 4009(j)(5), substituted “subparagraph (D)” for “subparagraph (E)”.


Subsec. (b)(3)(B). Pub. L. 100–203–§ 4006(b)(2)(B), struck out subpar. (C) which read as follows: “If the Secretary determines, for a fiscal year, that the aggregate payment amounts under this subchapter for such other capital-related costs for payments attributable to portions of cost reporting periods occurring during fiscal year 1987 and fiscal year 1988 shall approximate the aggregate payment amount under this subchapter that would have been made (taking into account the provisions of subparagraphs (A) and (B)) during that fiscal year but for the inclusion of such costs by the Secretary.”
Subsec. (b)(3)(B)(i)(II). Pub. L. 99–509, §9302(a)(1), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: “for fiscal years 1987 and 1988, a percentage determined by the Secretary pursuant to subsection (e)(4) of this section, but not to exceed the market basket percentage increase (as defined in clause (ii)) and


Subsec. (d)(1)(D). Pub. L. 99–272, §9102(c), struck out "cost reporting periods beginning, or before "discharges occurring in introductory provision, and "and after "percent," in cl. (ii), added cl. (iii), redesignated former cl. (iii) as (iv), and in cl. (iv) substituted "on or after October 1, 1986, and before October 1, 1985, and before October 1, 1986".


Pub. L. 99–272, §9104(b), inserted "(taking into account, for discharges occurring after September 30, 1986, the amendments made by section 904(a) of the Medicare and Medicaid Budget Reconciliation Amendments of 1985)" after "medical education costs".


Pub. L. 99–509, §9307(c)(1)(A), struck out Pub. L. 99–514, §1895(b)(1)(B), which had directed insertion of "If this formula under paragraph (5)(B) for determining payments for the indirect costs of medical education is changed for any fiscal year, the Secretary shall readjust the standardized amounts previously determined for each hospital to take into account the changes in that formula.

Pub. L. 99–272, §9101(c)(1), substituted “for each of fiscal years 1985 and 1986” for “for fiscal year 1985”.

Subsec. (d)(3)(B). Pub. L. 99–509, §9302(b)(1), inserted “for hospitals located in an urban area and for hospitals located in a rural area” after “paragraph (A)”, and inserted before the period “for hospitals located in such respective area”.


Pub. L. 99–509, §9307(c)(1)(A), struck out Pub. L. 99–514, §1895(b)(1)(C), which had directed a general amendment of cl. (i) to read as follows: “The Secretary shall further reduce each of the average standardized amounts by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment amounts which is the difference between—

“(I) the sum of the additional payment amounts under paragraph (5)(B) (relating to indirect costs of medical education) if the indirect teaching adjustment factor were equal to 1.159r (as ‘r’ is defined in paragraph (5)(B)(ii)), and

“(II) that sum using the factor specified in paragraph (5)(B)(ii).”

Subsec. (d)(3)(C)(iii). Pub. L. 99–509, §9307(c)(1)(B)(i), as amended by Pub. L. 100–203, §4009(j)(6)(A), struck out Pub. L. 99–514, §1895(b)(2)(B), which had added cl. (iii) reading as follows: “The Secretary shall further reduce each of the average standardized amounts by reducing the standardized amount for each hospital (as previously determined without regard to this clause) by a proportion equal to the proportion (established by the Secretary) of the amount of payments under this subsection based on DRG prospective payment amounts which are additional payments described in paragraph (5)(F) (relating to disproportionate share payments) for subsection (d) hospitals;”

Subsec. (d)(3)(D)(i)(I). Pub. L. 99–272, §9104(b)(3), inserted “or reduced” after “(B), and adjusted”.


Subsec. (d)(5)(B). Pub. L. 99–272, §9104(a), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2) of this section, except that in the computation under this subparagraph the Secretary shall use an educational adjustment factor equal to twice the factor provided under such regulations.

In determining such adjustment the Secretary shall not distinguish between those interns and residents who are employees of a hospital and those interns and residents who furnish services to a hospital but are not employees of such hospital.”


Pub. L. 99–272, §9106(a), inserted “and which shall not require a rural osteopathic hospital to have more than 3,000 discharges in a year in order to be classified as a rural referral center” before the period in second sentence.

Pub. L. 99–272, §9105(c), struck out “, and of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of this subchapter” after “in rural areas”.


Pub. L. 99–272, §9111(a), inserted provision authorizing the Secretary to adjust amount of payments to sole community hospitals that realize a significant increase in operating costs in a cost reporting period attributable to addition of new inpatient facilities or services in subcls. (I) and (II).

Subsec. (d)(5)(E). Pub. L. 99–509, §9302(g)(2), struck out subpar. (E) which read as follows: “The Secretary shall provide for an additional payment amount for any subsection (d) hospital equal to the reasonable costs incurred by such hospital for anesthesia services provided by a certified registered nurse anesthetist. Payment under this subparagraph shall be the only payment made to such hospital with respect to such services.”

Subsec. (a)(4). Pub. L. 98–21, §601(a)(2), inserted proviso that term ‘‘operating costs of inpatient hospital services’’ does not include costs of approved educational activities, or, with respect to costs incurred in cost reporting periods beginning prior to Oct. 1, 1986, capital-related costs, as defined by the Secretary.
Subsec. (b)(1). Pub. L. 98–92, §601(b)(1), (2), in provisions preceding subpar. (A), substituted ‘‘Notwithstanding section 1395f(b) of this title but subject to the provisions of section 1395e of this title’’ for ‘‘Notwithstanding sections 1395f(b) of this title, but subject to the provisions of sections 1395e of this title’’ and inserted ‘‘(other than a subsection (d) hospital, as defined in subsection (d)(1)(B) of this section)’’.
Pub. L. 98–21, §601(b)(3), inserted ‘‘(other than on the basis of a DRG prospective payment rate determined under subsection (d) of this section)’’ in provisions following subpar. (B).
Subsec. 97–448, §309(b)(14), substituted ‘‘section 1395f(b)’’ for ‘‘sections 1395f(b)’’ in provisions preceding subpar. (A).
Subsec. (b)(2). Pub. L. 98–21, §601(b)(4), struck out par. (2) which provided that par. (1) would not apply to cost reporting periods of hospitals beginning on or after Oct. 1, 1983.
Subsec. (b)(3)(B). Pub. L. 98–21, §601(b)(5)–(8), inserted ‘‘and subsection (d) of this section and except as provided in subsection (e) of this section’’ after ‘‘subsection (A)’’, inserted ‘‘or fiscal year’’ after ‘‘cost reporting period’’ such place it appears, inserted ‘‘before the beginning of the period or year’’ after ‘‘estimated by the Secretary’’, and substituted ‘‘will exceed’’ for ‘‘exceed’’.
Subsec. (b)(6). Pub. L. 98–21, §601(b)(9), added par. (6) and repealed a prior par. (6) which directed the Secretary to provide for an adjustment under this paragraph in the amount of payment otherwise provided a hospital under this subsection in the case of a hospital which, as of Aug. 15, 1982, was subject to FICA taxes and which was not subject to such taxes for part or all of a cost reporting period beginning on or after Oct. 1, 1982, that in making such adjustment for a cost reporting period the Secretary was to estimate the amount of the operating costs of inpatient hospital services that would have resulted if the hospital was subject to the FICA taxes during that period, that in making such estimate the Secretary was to reduce the amount of such FICA taxes that would have been paid (but not before zero) by the amount of costs which the hospital demonstrated to the satisfaction of the Secretary were incurred in the period for pensions, health, and other fringe benefits for employees (and former employees and family members) comparable to, and in lieu of, the benefits provided under subchapter II of this chapter and this subchapter, that if a hospital’s operating costs of inpatient hospital services estimated under subparagraph (B) was greater than the hospital’s operating costs of inpatient hospital services determined without regard to this paragraph for a cost reporting period, then the Secretary was to reduce the amount otherwise paid the hospital (respecting operating costs of inpatient hospital services) under this title (taking into account any limitation under subsection (a) of this section for the period by the amount by which (i) the amount that would have been paid the hospital if (I) the amount of the operating costs of inpatient hospital services estimated under subparagraph (B) were treated as the amount of the operating costs of inpatient hospital services and (II) subsection (a) of this section did not apply to the determination, exceeded (ii) the amount that would otherwise have been paid the hospital if subsection (a) of this paragraph did not apply, except that, in making such determination for cost reporting periods beginning on or after Oct. 1, 1984, clause (ii) of paragraph (1)(B) was to continue to apply.
Subsec. (b)(6)(C). Pub. L. 97–448, §309(b)(15), substituted ‘‘under this subsection, (taking into account any limitation under subsection (a) of this section)’’ for ‘‘under this subsection’’ in provisions preceding cl. (i).
Subsec. (c)(1). Pub. L. 98–21, §601(c)(1), added subpars. (D) and (E) and proviso following subpar. (D).
Subsec. (c)(3)(A). Pub. L. 98–21, §601(c)(2)(A), substituted ‘‘meets the requirements of subparagraphs (A), (D), and (E) of paragraph (1) and, if applicable, the requirements of paragraph (3)’’ for ‘‘meets the requirement of paragraph (1)(A)’’.
Subsec. (c)(3)(B). Pub. L. 98–21, §601(c)(2)(B), inserted ‘‘(or, if applicable, in paragraph (5)’’.
Subsec. (c)(4) to (6). Pub. L. 98–21, §601(c)(3), added pars. (4) to (6).
Subsec. (d). Pub. L. 98–21, §601(d)(2), (6), added subsec. (d) and redesignated former subsec. (d), relating to the elimination of lesser-of-cost-or-charges provisions, as subsec. (j) of section 1814 of act Aug. 14, 1933, which is classified to subsec. (j) of section 1395f of this title.
Subsecs. (e) to (g). Pub. L. 98–21, §601(e), added subsecs. (e) to (g).

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 110–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–192, title I, §102(b), June 25, 2010, 124 Stat. 1281, provided that: ‘‘The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [June 25, 2010].’’
Pub. L. 111–148, title III, §3401(p), Mar. 23, 2010, 124 Stat. 488, provided that: ‘‘Notwithstanding the preceding provisions of this section [amending this section and section 1396f, 1395m, 1396u, 1399tr, 1395yy, and 1395lff of this title], the amendments made by subsections (a), (c), and (d) [amending this section] shall not apply to discharges occurring before April 1, 2010.’’
Pub. L. 111–148, title V, §506(c), Mar. 23, 2010, 124 Stat. 66, provided that: ‘‘(1) IN GENERAL.—Except as otherwise provided, the Secretary of Health and Human Services shall implement the amendments made by this section [amending this section] in a manner so as to apply to cost reporting periods beginning on or after January 1, 1983.
(2) GME.—Section 1886(h)(4)(J) of the Social Security Act [42 U.S.C. 1395ww(h)(4)(J)], as added by subsection (a)(1)(B), shall apply to cost reporting periods beginning on or after July 1, 2009.
(3) IME.—Section 1886(d)(5)(B)(x)(III) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(B)(x)(III)], as added by subsection (b), shall apply to cost reporting periods beginning on or after October 1, 2001. Such section, as so added, shall not give rise to any inference as to how the law in effect prior to such date should be interpreted.’’

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110–173, title I, §114(e)(2), Dec. 29, 2007, 121 Stat. 2506, provided that: ‘‘Subsection (m)(2) of section 1886 of the Social Security Act [subsection (m)(2) of this section], as added by paragraph (1), shall not apply to discharges occurring on or after July 1, 2007, and before April 1, 2008.’’
paragraph (1) [amending this section] shall not apply to payment units occurring before April 1, 2001.'

Pub. L. 106–554, §1(a)(6) [title III, §300(d)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–494, provided that: ‘The amendment made by paragraph (1) [amending this section] is effective as if included in the enactment of BBA [Pub. L. 106–33].’


Pub. L. 106–554, §1(a)(6) [title V, §512(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–534, provided that: ‘The amendment made by subsection (a) [amending this section] shall apply to portions of cost reporting periods occurring on or after January 1, 2001.’

Effective Date of 1999 Amendment

Pub. L. 106–113, div. B, §1000(a)(6) [title I, §121(b)], Nov. 29, 1999, 113 Stat. 1358, 1501A–330, provided that: ‘The amendments made by subsection (a) [amending this section] apply to cost reporting periods beginning on or after October 1, 1999.’


Pub. L. 106–113, div. B, §1000(a)(6) [title III, §312(b)], Nov. 29, 1999, 113 Stat. 1358, 1501A–365, provided that: ‘The amendments made by subsection (a) [amending this section] apply to cost reporting periods beginning on or after July 1, 2000, to residency programs that began before, on, or after the date of the enactment of this Act [Nov. 29, 1999].’

Amendment by section 1000(a)(6) [title III, §321(b), (e), (f), (h), (k)(15)–(17)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106–113, set out as a note under section 1395i–4 of this title.

Amendment by section 1000(a)(6) [title IV, §401(a)] of Pub. L. 106–113 effective Jan. 1, 2000, see section 1000(a)(6) [title IV, §401(c)] of Pub. L. 106–113, set out as a note under section 1395i–4 of this title.

Amendment by section 1000(a)(6) [title IV, §402(b)], Nov. 29, 1999, 113 Stat. 1358, 1501A–370, provided that: ‘The amendments made by subsection (a) [amending this section] apply with respect to discharges occurring during cost reporting periods beginning on or after October 1, 1999.’

Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §407(a)(3)], Nov. 29, 1999, 113 Stat. 1358, 1501A–373, provided that: ‘(A) DGME.—The amendments made by paragraph (1) [amending this section] apply to cost reporting periods that begin on or after the date of the enactment of this Act [Nov. 29, 1999].’

‘(B) IME.—The amendment made by paragraph (2) [amending this section] applies to discharges occurring in cost reporting periods that begin on or after such date of enactment.’

Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §407(b)(3)], Nov. 29, 1999, 113 Stat. 1358, 1501A–374, provided that: ‘(A) DGME.—The amendment made by paragraph (1) [amending this section] applies to cost reporting periods beginning on or after April 1, 2000.’

‘(B) IME.—The amendment made by paragraph (2) [amending this section] applies to discharges occurring on or after April 1, 2000.’


‘(A) payments to hospitals under section 1886(b) of the Social Security Act (42 U.S.C. 1395w(b)(4)) for cost reporting periods beginning on or after April 1, 2000; and

‘(B) payments to hospitals under section 1886(d)(5)(B)(v) of such Act (42 U.S.C.
1385wwd(4)(j)(B)(v)) for discharges occurring on or after April 1, 2000.’’

**Effective Date of 1997 Amendment**
Amendment by section 4022(b) of Pub. L. 105–33 effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission and the Physician Payment Review Commission, see section 4022(c)(2) of Pub. L. 105–33, set out as an Effective Date: Transition; Transfer of Functions note under section 1395b–6 of this title.

Amendment by section 4201(c)(1), (4) 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.

Section 420(b) of Pub. L. 105–33 provided that: ‘‘The amendments made by subsection (a) [amending this section and provisions set out as a note below] shall apply with respect to discharges occurring on or after October 1, 1997.’’

Section 4405(d) of Pub. L. 105–33 provided that: ‘‘The amendments made by this section [amending this section] apply to discharges occurring after September 30, 1997.’’

Section 4411(e) of Pub. L. 105–33 provided that: ‘‘The amendments made by subsections (a) and (c) [amending this section] shall apply with respect to cost reporting periods beginning on or after October 1, 1997.’’

Section 4411(a)(2) of Pub. L. 105–33 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to discharges occurring on or after October 1, 1995.’’

Section 4411(b)(2) of Pub. L. 105–33 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after the date of the enactment of this Act [Aug. 5, 1997].’’

Section 4411(a)(2) of Pub. L. 105–33 provided that: ‘‘The amendments made by paragraph (1) [amending this section] shall apply to hospitals or units that first qualify as a hospital or unit described in section 1886(d)(1)(B) (42 U.S.C. 1395ww(d)(1)(B)) for cost reporting periods beginning on or after October 1, 1997.’’

Section 4422(c) of Pub. L. 105–33 provided that: ‘‘The amendments made by this section [amending this section] shall apply to cost reporting periods beginning on or after the date of the enactment of this Act [Nov. 5, 1997].’’

Section 4422(a)(2) of Pub. L. 105–33 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to hospitals or units that first qualify as a hospital or unit described in section 1886(d)(1)(B) (42 U.S.C. 1395ww(d)(1)(B)) for cost reporting periods beginning on or after October 1, 1997.’’

Section 4627(b) of Pub. L. 105–33 provided that: ‘‘The amendments made by subsection (a) [amending this section] shall apply—

‘‘(1) in the case of any services provided during the day immediately preceding the date of a patient’s admission (without regard to whether the services are related to the admission), to services furnished on or after the date of the enactment of this Act [Nov. 5, 1990] and before October 1, 1991; and

‘‘(2) in the case of diagnostic services (including clinical diagnostic laboratory tests), to services furnished on or after January 1, 1991; and

‘‘(3) in the case of any other services, to services furnished on or after October 1, 1991.’’

Section 13563(c)(2) of Pub. L. 101–66 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to payments under section 1886(h) of the Social Security Act (subsec. (h) of this section) for cost reporting periods beginning on or after October 1, 1992.’’

**Effective Date of 1990 Amendment**
Section 4002(a)(2) of Pub. L. 101–508 provided that: ‘‘The amendments made by paragraph (1) [amending this section] shall apply to payments for discharges occurring on or after January 1, 1991.’’

Section 4002(b)(2) of Pub. L. 101–508 provided that: ‘‘The amendments made by paragraphs (1), (3), and (4)(B) [amending this section] shall apply to discharges occurring on or after January 1, 1991, and the amendment made by paragraph (4)(A) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239].’’

Section 4002(c)(3) of Pub. L. 101–508 provided that: ‘‘The amendments made by paragraph (1) and paragraph (2)(A) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239].’’

**Effective Date of 1994 Amendment**
Section 101(a)(2) of Pub. L. 103–32 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall take effect as if included in the enactment of OBRA–1994 [Pub. L. 101–239].’’

Section 153(b) of Pub. L. 103–432 provided that: ‘‘The amendment made by subsection (a) [amending this section] shall apply as if included in the enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99–272).’’

**Effective Date of 1993 Amendment**
Section 13501(b)(3) of Pub. L. 103–66 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to discharges occurring on or after October 1, 1991.’’

Section 13563(b)(2) of Pub. L. 101–66 provided that: ‘‘The amendments made by paragraphs (1)(A) and (1)(B) [amending this section] shall take effect on July 1, 1995, and the date of the enactment of this Act [Aug. 10, 1993], respectively.’’

Section 13563(c)(2) of Pub. L. 101–66 provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to payments under section 1886(h) of the Social Security Act (subsec. (h) of this section) for cost reporting periods beginning on or after October 1, 1992.’’

**Effective Date of 1990 Amendment**
Section 4002(a)(2) of Pub. L. 101–508 provided that: ‘‘The amendments made by paragraph (1) [amending this section] shall apply to payments for discharges occurring on or after January 1, 1991.’’

Section 4002(b)(2) of Pub. L. 101–508 provided that: ‘‘The amendments made by paragraphs (1), (3), and (4)(B) [amending this section] shall apply to discharges occurring on or after January 1, 1991, and the amendment made by paragraph (4)(A) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239].’’

Section 4002(c)(3) of Pub. L. 101–508 provided that: ‘‘The amendments made by paragraph (1) and paragraph (2)(A) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239].’’

**Effective Date of 1989 Amendment**
Section 6003(a)(2) of Pub. L. 101–239 provided that: ‘‘The amendments made by paragraph (1) [amending this section] shall apply to payments for discharges occurring on or after January 1, 1990.’’
Section 6003(c)(4) of Pub. L. 101–239 provided that:

"The amendments made by this subsection [amending this section] shall apply with respect to discharges occurring on or after April 1, 1990."

Section 6003(b)(7) of Pub. L. 101–239 provided that:

"The amendments made by paragraphs (3) and (4) [amending this section] shall apply to discharges occurring on or after April 1, 1990."

Section 6004(a)(3) of Pub. L. 101–239 provided that:

"The amendments made by this subsection [amending this section] shall apply with respect to cost reporting periods beginning on or after October 1, 1989, except that—

(A) in the case of a hospital classified by the Secretary of Health and Human Services as a hospital involved extensively in treatment for or research on cancer under section 1886(d)(5)(I) of the Social Security Act [subsec. (d)(5)(I) of this section] (as redesignated by section 6709(e)(1)(A) after the date of the enactment of this Act [Dec. 19, 1989]), such amendments shall apply with respect to cost reporting periods beginning on or before the date of such classification.

(B) in the case of a hospital that is not described in subparagraph (A), such amendments shall apply with respect to portions of cost reporting periods or discharges occurring during and after fiscal year 1987 for purposes of section 1886(g) of the Social Security Act [subsec. (g) of this section], and

(C) such amendments shall take effect 30 days after the date of the enactment of the Medicare Catastrophic Coverage Act of 1988, payment under title XVIII of the Social Security Act [subsec. (d)(1)(A) of this section] for discharges occurring during fiscal year 1987 is deemed to have been such percentage increase as amended by subsection (a)."

Section 6007 of Pub. L. 101–239 provided that:

"(A) in the case of a hospital classified by the Secretary of Health and Human Services as a hospital involved extensively in treatment for or research on cancer under section 1886(d)(5)(I) of the Social Security Act [subsec. (d)(5)(I) of this section] (as redesignated by section 6709(e)(1)(A) after the date of the enactment of this Act [Dec. 19, 1989]), such amendments shall apply with respect to cost reporting periods beginning on or before the date of such classification.

(B) in the case of a hospital that is not described in subparagraph (A), such amendments shall apply with respect to portions of cost reporting periods or discharges occurring during and after fiscal year 1987 for purposes of section 1886(g) of the Social Security Act [subsec. (g) of this section], and

(C) such amendments shall take effect 30 days after the date of the enactment of the Medicare Catastrophic Coverage Act of 1988, payment under title XVIII of the Social Security Act [subsec. (d)(1)(A) of this section] for discharges occurring during fiscal year 1987 is deemed to have been such percentage increase as amended by subsection (a)."

Section 6008 of Pub. L. 101–239 provided that:

"The amendments made by this subsection [amending this section] shall apply with respect to cost reporting periods beginning on or after April 1, 1990."

Section 6009(c) of Pub. L. 101–239 provided in part that:

"The amendments made by that section to section 6011(d) of Pub. L. 101–239, set out above, are effective as if included in the enactment of Pub. L. 101–239."

Section 6010 of Pub. L. 101–239 provided that:

"The amendments made by subsection (a) [amending this section] shall become effective with respect to cost reporting periods beginning on or after April 1, 1990."

**Effective Date of 1988 Amendments**

Amendment by section 1018(c)(1) of Pub. L. 100–647 effective, except as otherwise provided, as if included in the provision of the Tax Reform Act of 1986, Pub. L. 99–514, to which such amendment relates, see section 1019(a) of Pub. L. 100–647, set out as a note under section 1 of Title 26, Internal Revenue Code.


Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to Omnibus Budget Reconciliation Act of 1987 (effective date note under section 101 of Title 1, General Provisions).

**Effective Date of 1987 Amendments**

Section 4002(g) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(b)(1)(I), July 1, 1988, 102 Stat. 769, provided that:

"(1) PPS hospitals, DRG portion of payment.—In the case of a subsection (d) hospital (as defined in paragraph (d)—

(A) the amendments made by subsections (a) and (c) [amending this section] shall apply to payments made under section 1886(d)(1)(A)(iii) of the Social Security Act [subsec. (d)(1)(A)(iii) of this section] on the basis of discharges occurring on or after April 1, 1988, and

(B) for discharges occurring on or after October 1, 1988, the applicable percentage increase (as defined in section 1886(b)(3)(B) of such Act [subsec. (b)(3)(B) of this section]) for discharges occurring during fiscal year 1987 is deemed to have been such percentage increase as amended by subsection (a).

(2) PPS sole community hospitals, hospital specific portion of payment.—In the case of a subsection (d) hospital which receives payments made under section 1886(d)(1)(A) of the Social Security Act [subsec. (d)(1)(A) of this section] because it is a sole community hospital—

(A) the amendment made by subsections (a) and (c) [amending this section] shall apply to payments under section 1886(d)(1)(A)(ii)(I) of the Social Security Act made on the basis of discharges occurring during a cost reporting period of a hospital, for the hospital’s cost reporting period beginning on or after October 1, 1987,

(B) notwithstanding subparagraph (A), for cost reporting period beginning during fiscal year 1988, the applicable percentage increase (as defined in section 1886(b)(3)(B) of such Act [subsec. (b)(3)(B) of this section]) for the—

(i) first 51 days of the cost reporting period shall be 0 percent,

(ii) next 132 days of such period shall be 2.7 percent, and

(iii) remainder of such period of the cost reporting period shall be the applicable percentage increase (as so defined, as amended by subsection (a)); and

(3) PPS-exempt hospitals.—In the case of a hospital that is not a subsection (d) hospital—

(A) the amendments made by subsection (e) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1987;

(B) notwithstanding subparagraph (A), for the hospital’s cost reporting period beginning during fiscal year 1988, payment under title XVIII of the Social Security Act [this subchapter] shall be made as though the applicable percentage increase described in section 1886(b)(3)(B) of such Act [subsec. (b)(3)(B) of this section] were equal to the product of 2.7 percent and the ratio of 315 to 366; and

(C) for cost reporting periods beginning on or after October 1, 1988, the applicable percentage increase (as so defined) with respect to the cost reporting period beginning during fiscal year 1988 shall be deemed to have been 2.7 percent.

(4) Definition, regional floor, and technical and conforming amendments.—The amendments made by subsections (b) and (d) and paragraphs (1) and (2) of subsection (f) [amending this section and provisions set out as a note below] shall take effect on the date of the enactment of this Act [Dec. 22, 1987].

(5) Transition for large urban area rates.—In computing the average standardized amount for hospitals located in a large urban area or other urban area under section 1886(d)(3)(B) of the Social Security Act [subsec. (d)(3)(B) of this section] (as amended by subsection (c) for fiscal year 1988, the reference to the respective average standardized amount computed for the previous fiscal year under this subparagraph is deemed a reference to the average standardized amount com-
computed for hospitals located in an urban area for the 51-day period beginning on October 1, 1987.

“(6) DEFINITION.—In this subsection, the term ‘subsection (d) hospital’ has the meaning given to such term in section 1886(d)(1)(B) of the Social Security Act [subsec. (d)(1)(B) of this section].”  

Section 4003(e) of Pub. L. 100–203 provided that: “The amendments made by this section (amending this section) shall apply to payments for discharges occurring on or after October 1, 1988.”

Section 4005(a)(3) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(b)(4)(C)(ii), July 1, 1988, 102 Stat. 770, provided that: “This subsection [amending this section] shall apply to discharges occurring on or after October 1, 1986.”

Section 4005(c)(2)(A) of Pub. L. 100–203 provided that: “The amendments made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1987.”

Section 4006(b)(3) of Pub. L. 100–203 provided that: “The amendment made by subparagraph (A) [amending this section] shall apply to discharges occurring on or after April 1, 1988.”

Section 4006(b)(3) of Pub. L. 100–203 provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on October 1, 1987. The amendments made by paragraph (2) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1987.”

Section 4007(b)(2) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(b)(6)(B), July 1, 1988, 102 Stat. 770, provided that: “The amendment made by paragraph (1)(C) [amending this section] shall apply to hospital cost reporting periods beginning on or after October 1, 1989.”

Amendment by Pub. L. 100–95 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–95, set out as a note under section 1320a–7 of this title.

**Effective Date of 1986 Amendments**


Amendment by section 1865(b)(9) of Pub. L. 99–514 effective, except as otherwise provided, as if included in enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99–570, see section 1865(b)(3)(B) of Pub. L. 99–514, set out as a note under section 162 of Title 26, Internal Revenue Code.

Section 9302(a)(3) of Pub. L. 99–509 provided that: “The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1986 and, for purposes of section 1886(d) of the Social Security Act [subsec. (d) of this section], for cost reporting periods beginning and discharges occurring on or after October 1, 1986.”

Section 9302(b)(2) of Pub. L. 99–509 provided that: “The amendments made by subsection (a) [amending this section] shall apply to discharges occurring on or after October 1, 1986.”

Section 9302(d)(1)(B) of Pub. L. 99–509 provided that: “(i) Subject to clause (ii), the amendments made by subparagraph (A) [amending this section] shall apply to payments for discharges occurring on or after October 1, 1986.

“(ii) An appeal for classification of a rural hospital as a regional referral center, pursuant to the amendments made by subparagraph (A), which is filed before January 1, 1987, and which is not final, with respect to discharges occurring on or after October 1, 1986.”

Section 9303(b) of Pub. L. 99–509 provided that the amendments made by such section 9303(b) is effective for cost reporting periods beginning and discharges occurring (as the case may be) on or after Oct. 1, 1987.

Section 9303(d) of Pub. L. 99–509 provided that: “The amendments made by this section [amending this section] shall apply to discharges occurring on or after October 1, 1987.”

Section 9303(d) of Pub. L. 99–509 provided that: “The amendments made by subsections (a) and (b) [amending this section] shall apply to discharges occurring on or after October 1, 1986.”

Section 9307(c)(1) of Pub. L. 99–509 provided that the amendment made by such section 9307(c)(1) is effective as if included in the enactment of the Tax Reform Act of 1986 (Pub. L. 99–514), if H.Con.Res. 395, 99th Congress, 2d Session, is not adopted. H.Con.Res. 395 was not adopted.

Section 9314(b) of Pub. L. 99–509 provided that: “The amendments made by subsection (a) [amending this section] shall apply to payments for approved residency training programs as of July 1, 1987.”

Amendment by section 9320(g) 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.

Section 9322(e)(3)(B) of Pub. L. 99–509 provided that: “The amendments made by paragraph (2) [amending this section] shall take effect beginning with fiscal year 1988.”

Section 9101(d) of Pub. L. 99–272 provided that: “The amendment made by subsection (b) [amending section 5(c) of Pub. L. 99–107, set out below] shall take effect on March 15, 1986, and the amendments made by subsection (c) [amending this section] shall take effect on the date of the enactment of this Act (Apr. 7, 1986).”

Section 9101(e) of Pub. L. 99–272 provided that: “(1) PPS hospitals, DRG portion of payment.—In the case of a subsection (d) hospital (as defined in paragraph (4))—

“(A) the amendment made by subsection (b) [amending this section] shall apply to payments made under section 1886(d)(1)(A) of such Act [subsec. (d)(1)(A) of this section] made on the basis of discharges occurring on or after May 1, 1986; and

“(B) for discharges occurring on or after October 1, 1986, the applicable percentage increase (described in section 1886(b)(3)(B) [subsec. (b)(3)(B) of this section]) for discharges occurring during fiscal year 1986 shall be deemed to have been ½ percent.

“(2) PPS hospitals, hospital specific portion of payment.—In the case of a subsection (d) hospital—

“(A) the amendment made by subsection (b) [amending this section] shall apply to payments made under section 1886(d)(1)(A) of such Act [subsec. (d)(1)(A) of this section] made on the basis of discharges occurring on or after May 1, 1986; and

“(B) notwithstanding subparagraph (A), for the cost reporting period beginning during fiscal year 1986, the
applicable percentage increase (as defined in section 1886(b)(3)(B) of such Act [subtitle (b)(3)(B) of this section]) for the—

- first 7 months of the cost reporting period shall be 0 percent; and
- (ii) for the remaining 5 months of the cost reporting period shall be ½ percent; and
- (C) for cost reporting periods beginning on or after October 1, 1986, the applicable percentage increase (as so defined) with respect to the cost reporting period shall not be deemed to have been ½ percent.

3. PPS-EXEMPT HOSPITALS.—In the case of a hospital that is not a subsection (d) hospital—

- (A) the amendment made by subsection (b) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1985; and
- (B) notwithstanding subparagraph (A), for the hospital’s cost reporting period beginning during fiscal year 1986, payment under title XVIII of the Social Security Act [this subchapter] shall be made as though the applicable percentage increase described in section 1886(b)(3)(B) of the Social Security Act [subtitle (b)(3)(B) of this section] were equal to 75 percent; and
- (C) for cost reporting periods beginning on or after October 1, 1986, the applicable percentage increase (as so defined) with respect to the cost reporting period beginning during fiscal year 1986 shall be deemed to have been ½ percent.

4. DEFINITION.—In this subsection, the term ‘subsection (d) hospital’ has the meaning given such term in section 1886(d)(1)(B) of the Social Security Act [subtitle (d)(1)(B) of this section].

5. Section 9102(d) of Pub. L. 99–272 provided that:

- (1) DELAY IN FINAL TRANSITION.—The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Apr. 7, 1986].

6. CHANGE IN HOSPITAL SPECIFIC PERCENTAGE.—The amendments made by subsection (b) [amending this section] shall apply:

- (A) to cost reporting periods beginning on or after October 1, 1985, but
- (B) notwithstanding subparagraph (A), for a hospital’s cost reporting period beginning during fiscal year 1986, payment under section 1885(b)(1)(A) of the Social Security Act [subtitle (d)(1)(A) of this section]—

  - (i) during the first 7 months of the period the ‘target percentage’ is 50 percent and the ‘DRG percentage’ is 5 percent, and
  - (ii) during the remaining 5 months of the period the ‘target percentage’ is 55 percent and the ‘DRG percentage’ is 5 percent.

7. CHANGE IN BLENDED RATE.—The amendments made by subsection (c) [amending this section] shall apply:

- (A) to cost reporting periods beginning on or after October 1, 1986, but
- (B) notwithstanding subparagraph (A), for a hospital’s cost reporting period beginning during fiscal year 1986, payment under title XIX of the Social Security Act [subchapter (d)(1)(B) of this section]—

  - (i) during the first 7 months of the period the ‘target percentage’ is 50 percent and the ‘DRG percentage’ is 5 percent, and
  - (ii) during the remaining 5 months of the period the ‘target percentage’ is 25 percent and the ‘DRG percentage’ is 15 percent.

8. EFFECTIVE AND TERMINATION DATES OF 1984 AMENDMENTS

Amendment by Pub. L. 98–617 effective as if originally included in the Deficit Reduction Act of 1984, Pub. L. 98–369, see section 3(c) of Pub. L. 98–617, set out as a note under section 1395f of this title.

Section 2307(b)(2) of Pub. L. 98–369 provided that:

“...The amendment made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1984...”

Section 2310(b) of Pub. L. 98–369 provided that: “The amendments made by this section [amending this section] shall apply to hospital cost reporting periods beginning on or after July 1, 1985...”

Stat. 2424, provided that: “The amendments made by subsections (a) and (b) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1984, and before January 1, 1989. In the case of a cost reporting period that begins before January 1, 1989, but ends after such date, additional payments under the amendment made by subsection (a) shall be proportionately reduced to reflect the portion of the period occurring after such date.”

Amendment by section 2313(a), (b), (d) of Pub. L. 98–21 effective July 18, 1984, see section 2313(e) of Pub. L. 98–21, set out as an Effective Date of 1984 Amendment note under section 1395y of this title.

Section 2313(g) of Pub. L. 98–21 provided that: “The amendments made by subsection (a) [amending this section and sections 1395i–2 and 1395cc of this title and enacting and amending provisions set out as notes under this section] shall be effective as though they had been included in the amendments of 1983 (Public Law 98–21).”

Amendment by section 2354(b)(1)(A)–(C) of Pub. L. 98–21 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 an Effective Date of 1984 Amendment note under section 1320a–1 of this title.

**Effective Date of 1983 Amendments**

Section 601(b)(9) of Pub. L. 98–21 provided that the repeal of subsec. (b)(6) of this section is effective with respect to cost reporting periods beginning on or after October 1, 1984, and that the enactment of a new subsec. (b)(6) of this section is effective with respect to cost reporting periods beginning on or after October 1, 1983.

Section 604 of title VI of Pub. L. 98–369, set out as a note under section 1395y of this title, enacting provisions set out as notes under this section, shall be effective as if originally included as a part of this section as this section was added by the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248, see section 309(c)(2) of Pub. L. 97–248, set out as a note under section 426–1 of this title.

**Effective Date**

Section 101(b)(1) of Pub. L. 98–248 provided that: “The amendments made by subsection (a) [enacting this section and amending section 1395x of this title] shall apply to cost reporting periods beginning on or after October 1, 1982.”

**Regulations**

Section 4003(c) of Pub. L. 101–508 provided that: “The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this section [amending this section and enacting provisions set out as a note above].”

Section 2313(f)(2) of Pub. L. 98–21 provided that: “Notwithstanding section 604(c) of the Social Security Amendments of 1982 [section 604(c) of Pub. L. 98–21, set out above], the Secretary of Health and Human Services shall cause to be published in the Federal Register proposed regulations to carry out subsection (c) of section 1386 of the Social Security Act [subsec. (c) of this section] not later than July 1, 1984, and allow for a period of 45 days for public comment thereon. After consideration of the comments received, the Secretary shall cause to be published in the Federal Register final regulations to carry out such subsection not later than October 1, 1984.”

Section 101(b)(2)(A) of Pub. L. 97–248 provided that: “The Secretary of Health and Human Services shall first issue such final regulations (whether on an interim or other basis) before October 1, 1982, as may be necessary to implement such amendments [amendments by section 101(a) of Pub. L. 97–248, enacting this section and amending section 1395x of this title] on a timely basis. If such regulations are promulgated on an interim final basis, the Secretary shall take such further action as may be necessary to provide opportunity for public comment, and appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than March 31, 1983.”

**Construction of 2010 Amendment**

Pub. L. 111–192, title I, §102(e), June 25, 2010, 124 Stat. 1262, provided that: “Nothing in the amendments made by this section [amending this section] shall be construed as changing the policy described in section 1866(a)(4) of the Social Security Act (42 U.S.C. 1395ww(a)(4)), as applied by the Secretary of Health and Human Services before the date of the enactment of this Act [June 25, 2010], with respect to diagnostic services.”

Pub. L. 111–148, title V, §550(c), Mar. 23, 2010, 124 Stat. 660, provided that: “The amendments made by this section [amending this section] shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act [Mar. 23, 2010] on the issue of payment for indirect costs of medical education under
section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) or for direct graduate medical education costs under section 1886(h) of such Act (42 U.S.C. 1395ww(h))."

Pub. L. 111–148, title V, § 5506(c), Mar. 23, 2010, 124 Stat. 662, provided that: "The amendments made by this section [amending this section] shall not be applied in a manner that requires reopening of any settled cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act [Mar. 23, 2010] on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) or for direct graduate medical education costs under section 1886(h) of such Act (42 U.S.C. 1395ww(h))."

TRANSFER OF FUNCTIONS
Prospective Payment Assessment Commission (ProPAC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 4022(c)(2), (3) of Pub. L. 110–316, set out as a note under section 1386d–8 of this title. Section 4022(c)(2), (3) further provided that MedPAC was to be responsible for preparation and submission of reports required by law to be submitted by ProPAC, and that, for that purpose, any reference in law to ProPAC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.

SPECIAL RULE FOR FISCAL YEAR 2011 AND ADJUSTMENT FOR CERTAIN HOSPITALS IN FISCAL YEAR 2011

"(1) IN GENERAL.—Subject to subparagraph (B), for purposes of implementation of the amendment made by paragraph (1) [amending section 106(a) of div. B of Pub. L. 109–316, set out as a note under this section], including (notwithstanding paragraph (3) of section 117(a) of the Medicare, Medicaid, and SCHIP Extension Act of 2007 [Public Law 110–173] [set out as a note under this section], as amended by section 124(a) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275) for purposes of the implementation of paragraph (2) of such section 117(a), during fiscal year 2011, the Secretary of Health and Human Services shall use the hospital wage index that was promulgated by the Secretary of Health and Human Services in the Federal Register on August 16, 2010 (75 Fed. Reg. 50042), and any subsequent corrections.

"(2) EXCEPTION.—Beginning on April 1, 2011, in determining the wage index applicable to hospitals that qualify for wage index reclassification, the Secretary shall include the average hourly wage data of hospitals whose reclassification was extended pursuant to section 1886(g)(4) of the Social Security Act.

"(3) ADJUSTMENT FOR CERTAIN HOSPITALS IN FISCAL YEAR 2011.—

"(A) IN GENERAL.—In the case of a subsection (d) hospital (as defined in subsection (d)(1)(B) of section 1886 of the Social Security Act (42 U.S.C. 1395ww)) with respect to which—

"(1) a reclassification of its wage index for purposes of such section was extended pursuant to the amendment made by paragraph (1); and

"(ii) the wage index applicable to such hospital for the period beginning on October 1, 2010, and ending on March 31, 2011, was lower than for the period beginning on April 1, 2011, and ending on September 30, 2011, by reason of the application of paragraph (2)(B);

"the Secretary shall pay such hospital an additional payment that reflects the difference between the wage index for such periods.

"(B) TIMEFRAME FOR PAYMENTS.—The Secretary shall make payments required under subparagraph (A) by not later than December 31, 2011."


NO REOPENING OF PREVIOUSLY BUNDED CLAIMS
Pub. L. 111–192, title I, § 102(c), June 25, 2010, 124 Stat. 1281, provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services may not reopen a claim, adjust a claim, or make a payment pursuant to any request for payment under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), submitted by an entity (including a hospital or an entity wholly owned or operated by the hospital) for services described in paragraph (2) for purposes of treating, as unrelated to a patient's inpatient admission, services provided during the 3 days (or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) immediately preceding the date of the patient's inpatient admission.

"(2) SERVICES DESCRIBED.—For purposes of paragraph (1), the services described in this paragraph are other services related to the admission (as described in section 1886(a)(4) of the Social Security Act (42 U.S.C. 1395ww(a)(4)), as amended by subsection (a)) which were previously included on a claim or request for payment submitted under part A of title XVIII of such Act (42 U.S.C. 1395c et seq.) for which a reopening, adjustment, or request for payment under part B of such title (42 U.S.C. 1395 et seq.), was not submitted prior to the date of the enactment of this Act [June 25, 2010]."

IMPLEMENTATION OF AMENDMENT BY PUBL. L. 111–192
Pub. L. 111–192, title I, § 102(d), June 25, 2010, 124 Stat. 1281, provided that: "Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of this section [amending this section and enacting provisions set out as notes under this section] (and amendments made by this section) by program instruction or otherwise."

PAYMENT FOR QUALIFYING HOSPITALS
Pub. L. 111–152, title I, § 1109, Mar. 30, 2010, 124 Stat. 1051, provided that:

"(a) IN GENERAL.—From the amount available under subsection (b), the Secretary of Health and Human Services shall provide for a payment to qualifying hospitals (as defined in subsection (d)) for fiscal years 2011 and 2012 of the amount determined under subsection (c).

"(b) AMOUNTS AVAILABLE.—There shall be available from the Federal Hospital Insurance Trust Fund $400,000,000 for payments under this section for fiscal years 2011 and 2012.

"(c) PAYMENT AMOUNT.—The amount of payment under this section for a qualifying hospital shall be determined, in a manner consistent with the amount available under subsection (b), in proportion to the portion of the amount of the aggregate payments under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) to the hospital for fiscal year 2009 bears to the sum of all such payments to all qualifying hospitals for such fiscal year.

"(d) QUALIFYING HOSPITAL DEFINED.—In this section, the term "qualifying hospital" means a subsection (d) hospital (as defined in subsection (d)(1)(B) of section 1886 of the Social Security Act (42 U.S.C. 1395ww))."
hospital (as defined for purposes of section 1886(d) of the Social Security Act) that is located in a county that ranks, based upon its ranking in age, sex, and race adjusted spending for benefits under parts A and B under title XVIII of such Act [42 U.S.C. 1395 et seq.; 42 U.S.C. 1395j et seq.] per enrollee, within the lowest quartile of such counties in the United States.”

VALUE-BASED PURCHASING DEMONSTRATION PROGRAMS


“(1) VALUE-BASED PURCHASING DEMONSTRATION PROGRAM FOR INPATIENT CRITICAL ACCESS HOSPITALS.—

“(A) Establishment.—In general.—Not later than 2 years after the date of enactment of this Act [Mar. 23, 2010], the Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) shall establish a demonstration program under which the Secretary establishes a value-based purchasing program under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], for critical access hospitals (as defined in paragraph (1) of section 1861(mm) of such Act [42 U.S.C. 1395x(mm)]) with respect to inpatient critical access hospital services (as defined in paragraph (2) of such section) in order to test innovative methods of measuring and rewarding quality and efficient health care furnished by such hospitals.

“(B) Duration.—The demonstration program under this paragraph shall be conducted for a 3-year period.

“(C) Reporting.—Not later than 18 months after the completion of the demonstration program under this paragraph, the Secretary shall submit to Congress a report on the demonstration program under this paragraph together with—

“(i) recommendations on the establishment of a permanent value-based purchasing program under the Medicare program for applicable hospitals with respect to inpatient hospital services; and

“(ii) recommendations for such other legislation and administrative action as the Secretary determines appropriate.

REFORMING THE MEDICARE HOSPITAL WAGE INDEX SYSTEM

Pub. L. 111–148, title III, §3137(b), (c), Mar. 23, 2010, 124 Stat. 438, 439, provided that:

“(B) PLAN FOR REFORMING THE MEDICARE HOSPITAL WAGE INDEX SYSTEM

“(1) In general.—Not later than December 31, 2011, the Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall submit to Congress a report that includes a plan to reform the hospital wage index system under section 1886 of the Social Security Act [42 U.S.C. 1395ww].

“(2) Details.—In developing the plan under paragraph (1), the Secretary shall take into account the goals for reforming such system set forth in the Medicare Payment Advisory Commission July 2007 report entitled ‘Report to Congress: Promoting Greater Efficiency in Medicare’, including establishing a new hospital compensation index system that—

“(A) uses Bureau of Labor Statistics data, or other data or methodologies, to calculate relative wages for each geographic area involved;

“(B) minimizes wage index adjustments between and within metropolitan statistical areas and statewide rural areas;

“(C) includes methods to minimize the volatility of wage index adjustments that result from implementation of policy, while maintaining budget neutrality in applying such adjustments;

“(D) takes into account the effect that implementation of the system would have on health care providers and on each region of the country;

“(E) addresses issues related to occupational mix, such as staffing practices and ratios, and any evidence on the effect on quality of care or patient safety as a result of the implementation of the system; and

“(F) provides for a transition.

“(3) Consultation.—In developing the plan under paragraph (1), the Secretary shall consult with relevant affected parties.
“(c) Use of particular criteria for determining reclassifications.—Notwithstanding any other provision of law, in making decisions on applications for reclassification of a subsection (d) hospital (as defined in paragraph (1)(B) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)(1)) for the purposes described in paragraph (10)(D)(v) of such section for fiscal years 2011 and each subsequent fiscal year until the first fiscal year beginning on or after the date that is 1 year after the Secretary of Health and Human Services submits the report to Congress under subsection (b), the Geographic Classification Review Board established under paragraph (10) of such section shall use the average hourly wage comparison criteria used in making such decisions as of September 30, 2008. The preceding sentence shall be effective in a budget neutral manner.”

APPLICATION OF BUDGET NEUTRALITY ON A NATIONAL BASIS IN THE CALCULATION OF THE MEDICARE HOSPITAL WAGE INDEX FLOOR

Pub. L. 111–148, title III, § 3141, Mar. 23, 2010, 124 Stat. 441, provided that: “In the case of discharges occurring on or after October 1, 2010, for purposes of applying section 4410 of the Balanced Budget Act of 1997 (section 4410 of Pub. L. 105–33, set out as a note under this section) (42 U.S.C. 1395ww) note) and paragraph (h)(4) of section 422.64 of title 42, Code of Federal Regulations, the Secretary of Health and Human Services shall administer subsection (b) of such section 4410 and paragraph (e)(4) of such section 422.64 in the same manner as the Secretary administered such subsection (b) and paragraph (e) for discharges occurring during fiscal year 2008 (through a uniform, national adjustment to the area wage index).”

EFFECT ON TEMPORARY FTE CAP ADJUSTMENTS

Pub. L. 111–148, title V, § 5506(d), Mar. 23, 2010, 124 Stat. 662, provided that: “The Secretary of Health and Human Services shall give consideration to the effect of the amendments made by this section [amending this section] on any temporary adjustment to a hospital’s FTE cap under section 413.79(h) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this Act [Mar. 23, 2010]) in order to ensure that there is no duplication of FTE slots. Such amendments shall not affect the application of section 1395ww(h)(4)(H)(v) of the Social Security Act (42 U.S.C. 1395ww(h)(4)(H)(v)).”

GRADUATE NURSE EDUCATION DEMONSTRATION


“(1) ESTABLISHMENT.—

“(A) IN GENERAL.—The Secretary shall establish a graduate nurse education demonstration under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) under which an eligible hospital may receive payment for the hospital’s reasonable costs (as described in paragraph (2)) for the provision of qualified clinical training to advance practice nurses.

“(B) NUMBER.—The demonstration shall include up to 5 eligible hospitals.

“(C) WRITTEN AGREEMENTS.—Eligible hospitals selected to participate in the demonstration shall enter into written agreements pursuant to subsection (b) in order to reimburse the eligible partners of the hospital the share of the costs attributable to each partner.

“(2) COSTS DESCRIBED.—

“(A) IN GENERAL.—Subject to subparagraph (B) and subsection (d), the costs described in this paragraph are the reasonable costs (as described in section 1861(v) of the Social Security Act (42 U.S.C. 1395x(v)) of each eligible hospital for the clinical training costs (as determined by the Secretary) that are attributable to providing advanced practice registered nurses with qualified training.

“(B) LIMITATION.—With respect to a year, the amount reimbursed under subparagraph (A) may not exceed the amount of costs described in subparagraph (A) that are attributable to an increase in the number of advanced practice registered nurses enrolled in a program that provides qualified training during the year and for which the hospital is being reimbursed under the demonstration, as compared to the average number of advanced practice registered nurses who graduated in each year during the period beginning on January 1, 2006, and ending on December 31, 2010 (as determined by the Secretary) from the graduate nursing education program operated by the applicable school of nursing that is an eligible partner of the hospital for purposes of the demonstration.

“(3) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq., 1395 et seq.) as may be necessary to carry out the demonstration.

“(4) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the implementation of this section.

“(b) WRITTEN AGREEMENTS WITH ELIGIBLE PARTNERS.—No payment shall be made under this section to an eligible hospital unless such hospital has in effect a written agreement with the eligible partners of the hospital. Such written agreement shall describe, at a minimum—

“(1) the obligations of the eligible partners with respect to the provision of qualified training; and

“(2) the obligation of the eligible hospital to reimburse such eligible partners applicable (in a timely manner) for the costs of such qualified training attributable to partner.

“(c) EVALUATION.—Not later than October 17, 2017, the Secretary shall submit to Congress a report on the demonstration. Such report shall include an analysis of the following:

“(1) The growth in the number of advanced practice registered nurses with respect to a specific base year as a result of the demonstration.

“(2) The growth for each of the specialties described in subparagraphs (A) through (D) of subsection (e)(1).

“(3) The costs to the Medicare program under title XVIII of the Social Security Act as a result of the demonstration.

“(4) Other items the Secretary determines appropriate and relevant.

“(d) FUNDING.—

“(1) IN GENERAL.—There is hereby appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, $50,000,000 for each of fiscal years 2012 through 2015 to carry out this section, including the design, implementation, monitoring, and evaluation of the demonstration.

“(2) FRACTION.—If the aggregate payments to eligible hospitals under the demonstration exceed $50,000,000 for a fiscal year described in paragraph (1), the Secretary shall prorate the payment amounts to each eligible hospital in order to ensure that the aggregate payments do not exceed such amount.

“(3) WITHOUT FISCAL YEAR LIMITATION.—Amounts appropriated under this subsection shall remain available without fiscal year limitation.

“(e) DEFINITIONS.—In this section:

“(1) ADVANCED PRACTICE REGISTERED NURSE.—The term ‘advanced practice registered nurse’ includes the following:

“(A) A clinical nurse specialist (as defined in subsection (aa)(5) of section 1861 of the Social Security Act (42 U.S.C. 1395x)).

“(B) A nurse practitioner (as defined in such subsection).

“(C) A certified registered nurse anesthetist (as defined in subsection (bb)(2) of such section).

“(D) A certified nurse-midwife (as defined in subsection (gg)(2) of such section).

“(2) APPLICABLE NON-HOSPITAL COMMUNITY-BASED CARE SETTING.—The term ‘applicable non-hospital hospital'.
community-based care setting' means a non-hospital community-based care setting which has entered into a written agreement (as described in subsection (b)) with the eligible hospital participating in the demonstration. Such settings include Federally qualified health centers, rural health clinics, and other non-hospital settings as determined appropriate by the Secretary.

"(3) APPLICABLE SCHOOL OF NURSING.—The term 'applicable school of nursing' means an accredited school of nursing (as defined in section 801 of the Public Health Service Act (42 U.S.C. 295)) which has entered into a written agreement (as described in subsection (b)) with the eligible hospital participating in the demonstration.

"(4) DEMONSTRATION.—The term 'demonstration' means the graduate nurse education demonstration established under subsection (a).

"(5) ELIGIBLE HOSPITAL.—The term 'eligible hospital' means a hospital (as defined in subsection (c) of section 1861 of the Social Security Act (42 U.S.C. 1395x)) or a critical access hospital (as defined in subsection (mm)(1) of such section) that has a written agreement in place with—

"(A) 1 or more applicable schools of nursing; and

"(B) 2 or more applicable non-hospital community-based care settings.

"(6) ELIGIBLE PARTNERS.—The term 'eligible partners' includes the following:

"(A) An applicable non-hospital community-based care setting.

"(B) An applicable school of nursing.

"(7) QUALIFIED TRAINING.—

"(A) IN GENERAL.—The term 'qualified training' means training—

"(i) that provides an advanced practice registered nurse with the clinical skills necessary to provide primary care, preventive care, transitional care, chronic care management, and other services appropriate for individuals entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.); or

"(ii) subject to subparagraph (B), at least half of which is provided in a non-hospital community-based care setting.

"(B) WAIER OF REQUIREMENT HALF OF TRAINING BE PROVIDED IN NON-HOSPITAL COMMUNITY-BASED CARE SETTING IN CERTAIN AREAS.—The Secretary may waive the requirement under subparagraph (A)(i) with respect to eligible hospitals located in rural or medically underserved areas.

"(8) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.

PAYMENT FOR LONG-TERM CARE HOSPITAL SERVICES


"(1) DELAY IN APPLICATION OF 25 PERCENT PATIENT THRESHOLD PAYMENT ADJUSTMENT.—The Secretary of Health and Human Services shall not apply, for cost reporting periods beginning on or after July 1, 2007, for a 5-year period—

"(A) section 412.536 of title 42, Code of Federal Regulations, or any similar provision, to freestanding long-term care hospitals or to a long-term care hospital, or satellite facility, that as of December 29, 2007, was co-located with an entity that is a provider-based, off-campus location of a subsection (d) hospital which did not provide services payable under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) at the off-campus location; and

"(B) such section or section 412.536 of title 42, Code of Federal Regulations, or any similar provisions, to a long-term care hospital identified by the amendment made by section 4417(a) of the Balanced Budget Act of 1997 (Public Law 105–33) [amending this section and enacting provisions set out as a note under this section].

"(2) PAYMENT FOR HOSPITALS WITHIN HOSPITALS.—

"(A) IN GENERAL.—Payment to an applicable long-term care hospital or satellite facility which is located in a rural area or which is co-located with an urban single or MSA dominant hospital under paragraphs (d)(1), (e)(1), and (e)(4) of section 112.534 of title 42, Code of Federal Regulations, shall not be subject to any payment adjustment under such section if more than 75 percent of the hospital's Medicare discharges (other than discharges described in paragraph (d)(2) or (e)(3) of such section) are admitted from a co-located hospital.

"(B) CO-LOCATED LONG-TERM CARE HOSPITALS AND SATTELITE FACILITIES.—

"(1) IN GENERAL.—Payment to an applicable long-term care hospital or satellite facility which is co-located with another hospital shall not be subject to any payment adjustment under section 412.534 of title 42, Code of Federal Regulations, if more than 50 percent of the hospital's Medicare discharges (other than discharges described in paragraph (d)(3) of such section) are admitted from a co-located hospital.

"(II) APPLICABLE LONG-TERM CARE HOSPITAL OR SATELLITE FACILITY DEFINED.—In this paragraph, the term 'applicable long-term care hospital or satellite facility' means a hospital or satellite facility that is subject to the transition rules under section 412.534(g) of title 42, Code of Federal Regulations or that is described in section 412.22(h)(3)(i) of such title.

"(C) EFFECTIVE DATE.—Subparagraphs (A) and (B) shall apply to cost reporting periods beginning on or after October 1, 2007 (or July 1, 2007, in the case of a satellite facility described in section 412.22(h)(3)(i) of title 42, Code of Federal Regulations) for a 5-year period.

"(3) NO APPLICATION OF VERY SHORT-STAY OUTLIER POLICY.—The Secretary shall not apply, for the 5-year period beginning on the date of the enactment of this Act, the amendments finalized on May 11, 2007 (72 Federal Register 26904, 26992) made to the short-stay outlier payment provision for long-term care hospitals contained in section 412.529(c)(3)(i) of title 42, Code of Federal Regulations, or any similar provision.

"(4) NO APPLICATION OF ONE-TIME ADJUSTMENT TO STANDARD AMOUNT.—The Secretary shall not, for the 5-year period beginning on the date of the enactment of this Act, make the one-time prospective adjustment to long-term care hospital prospective payment rates provided for in section 412.523(d)(3) of title 42, Code of Federal Regulations, or any similar provision.


MORATORIUM ON THE ESTABLISHMENT OF LONG-TERM CARE HOSPITALS, LONG-TERM CARE SATTELITE FACILITIES AND ON THE INCREASE OF LONG-TERM CARE HOSPITAL BEdS IN EXISTING LONG-TERM CARE HOSPITALS OR SATTELITE FACILITIES


"(1) IN GENERAL.—During the 5-year period beginning on the date of the enactment of this Act [Dec. 29, 2007], the Secretary of Health and Human Services shall impose a moratorium for purposes of the Medicare program under title XVIII of the Social Security Act [this subchapter]—

"(A) subject to paragraph (2), on the establishment and classification of a long-term care hospital or sat-
of this section] and continued stay at such hospitals, (B) subject to paragraph (3), on an increase of long-term care hospital beds in existing long-term care hospitals or satellite facilities.

(2) EXCEPTION FOR CERTAIN LONG-TERM CARE HOSPITALS.—The moratorium under paragraph (1)(A) shall not apply to a long-term care hospital that as of the date of the enactment of this Act—

(A) began its qualifying period for payment as a long-term care hospital under section 412.23(e) of title 42, Code of Federal Regulations, on or before the date of the enactment of this Act;

(B) has a binding written agreement with an outside, unrelated party for the actual construction, renovation, lease, or demolition for a long-term care hospital, and has expended, before the date of the enactment of this Act, at least 10 percent of the estimated cost of the project (or, if less, $2,500,000);

(C) has obtained an approved certificate of need in a State where one is required on or before the date of the enactment of this Act.

(3) EXCEPTION FOR BED INCREASES DURING MORATORIUM.—

(A) IN GENERAL.—Subject to subparagraph (B), the moratorium under paragraph (1)(B) shall not apply to an increase in beds in an existing hospital or satellite facility if the hospital or facility obtained a certificate of need for an increase in beds that is in a State for which such certificate of need is required and that was issued on or after April 1, 2005, and before December 29, 2007, or if the hospital or facility—

(i) is located in a State where there is only one other long-term care hospital; and

(ii) requests an increase in beds following the closure or the decrease in the number of beds of another long-term care hospital in the State.

(B) NO EFFECT ON CERTAIN LIMITATION.—The exception under subparagraph (A) shall not affect the limitation on increasing beds under sections 412.22(h)(3) and 412.22(f) of title 42, Code of Federal Regulations.

(4) EXCEPTION TO CERTAIN FACILITY DEFINED.—For purposes of this subsection, the term ‘existing’ means, with respect to a hospital or satellite facility, a hospital or satellite facility that received payment under the provisions of subpart O of part 412 of title 42, Code of Federal Regulations, as of the date of the enactment of this Act.

(5) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1889 of the Social Security Act (42 U.S.C. 1395ff), section 1878 of such Act (42 U.S.C. 1395oo), or otherwise, of the application of this subsection by the Secretary.

(6) EFFECTIVE DATE.—Subtitle C of division B of Public Law 109–432 (set out below) and the special exception reclassifications made under the authority of section 1886(d)(4)(A) of the Social Security Act (42 U.S.C. 1395ww(d)(4)(A)) and contained in the final rule promulgated by the Secretary in the Federal Register on August 11, 2004 (69 Fed. Reg. 49105, 49107).

(7) USE OF PARTICULAR WAGE INDEX.—For purposes of implementation of this subsection [par. (1) of this subsection amended section 188(a) of Pub. L. 109–332, set out below] in fiscal years 2008 and 2009, the Secretary shall use the hospital wage index that was promulgated by the Secretary in the Federal Register on October 10, 2007 (72 Fed. Reg. 57694), and any subsequent corrections.

CORRECTION OF APPLICATION OF WAGE INDEX DURING TAX RELIEF AND HEALTH CARE ACT EXTENSION


(1) In general.—The Secretary of Health and Human Services shall provide, under contracts with one or more appropriate fiscal intermediaries or Medicare administrative contractors under section 1874(a)(4)(G) of the Social Security Act (42 U.S.C. 1395kk–1(a)(4)(G)), for reviews of the medical necessity of admissions to long-term care hospitals (described in section 1886(d)(1)(B)(iv) of such Act [subsec. (d)(1)(B)(iv) of this section]) and continued stay at such hospitals, of individuals entitled to, or enrolled for, benefits under part A of title XVIII of such Act [part A of this subchapter] consistent with this subsection. Such reviews shall be made for discharges occurring on or after October 1, 2007.

(2) Review methodology.—The medical necessity reviews under paragraph (1) shall be conducted on an annual basis in accordance with rules specified by the Secretary. Such reviews shall—

(A) provide for a statistically valid and representative sample of admissions of such individuals suffi-

cient to provide results at a 95 percent confidence interval; and

(B) guarantee that at least 75 percent of overpayments received by long-term care hospitals due to medically unnecessary admissions and continued stays of individuals in long-term care hospitals will be identified and recovered and that related days of care will not be counted toward the length of stay recouped by the Secretary in the Federal Register on October 10, 2007 (72 Fed. Reg. 57694), and any subsequent corrections.

EXTENDING CERTAIN MEDICARE HOSPITAL WAGE INDEX RECLASSIFICATIONS


(2) SPECIAL EXCEPTION RECLASSIFICATIONS.—The Secretary of Health and Human Services shall extend for discharges occurring through the last date of the extension of reclassifications under section 106(a) of the Medicare Improvement[s] and Extension Act of 2006 (division B of Public Law 109–432—set out below), the special exception reclassifications made under the authority of section 1886(d)(4)(A) of the Social Security Act (42 U.S.C. 1395ww(d)(4)(A)) and contained in the final rule promulgated by the Secretary in the Federal Register on October 11, 2004 (69 Fed. Reg. 49105, 49107).

(3) USE OF PARTICULAR WAGE INDEX.—For purposes of implementation of this subsection [par. (1) of this subsection amended section 188(a) of Pub. L. 109–332, set out below] in fiscal years 2008 and 2009, the Secretary shall use the hospital wage index that was promulgated by the Secretary in the Federal Register on October 10, 2007 (72 Fed. Reg. 57694), and any subsequent corrections.
"(2) the wage index applicable for such hospital during such period was lower than the wage index applicable for such hospital during the period beginning on October 1, 2006, and ending on March 31, 2007, then the Secretary (of Health and Human Services) shall apply the higher wage index that was applicable for such hospital during the period beginning on October 1, 2006, and ending on March 31, 2007, if the Secretary determines that the applicability of the preceding sentence to a hospital will result in a hospital being owed additional reimbursement, the Secretary shall make such payments within 90 days after the settlement of the applicable cost report."
“(A) remuneration for purposes of section 1128B of the Social Security Act (42 U.S.C. 1320a-7b);”

“(B) a payment intended to induce a physician to reduce or limit services to a patient entitled to benefits under Medicare or a State plan approved under title XIX of such Act (subchapter XIX of this chapter) in violation of section 1128A of such Act (42 U.S.C. 1320a-7a);”

“(C) a financial relationship for purposes of section 1877 of such Act (42 U.S.C. 1395nn).”

“(2) PROTECTION FOR EXISTING ARRANGEMENTS.—In no case shall the failure to comply with the requirements described in paragraph (1) affect a finding made by the Inspector General of the Department of Health and Human Services prior to the date of the enactment of this Act (Feb. 8, 2006) that an arrangement between a hospital and a physician does not violate paragraph (1) or (2) of section 1128A(a) of the Social Security Act (42 U.S.C. 1320a-7(a) (42 U.S.C. 1320a-7a(a)).”

“(d) PROGRAM ADMINISTRATION.—

“(1) SOLICITATION OF APPLICATIONS.—By not later than 90 days before the date of the enactment of this Act (Feb. 8, 2006), the Secretary shall solicit applications for approval of a demonstration project, in such form and manner, and at such time specified by the Secretary.

“(2) NUMBER OF PROJECTS APPROVED.—The Secretary shall approve not more than 6 demonstration projects, at least 2 of which shall be located in a rural area.

“(3) DURATION.—The qualified gainsharing demonstration program under this section shall be conducted for the period beginning on January 1, 2007, and ending on December 31, 2009 (or September 30, 2011, in the case of a demonstration project in operation as of October 1, 2008).

“(e) REPORTS.—

“(1) INITIAL REPORT.—By not later than December 1, 2006, the Secretary shall submit to Congress a report on the number of demonstration projects that will be conducted under this section.

“(2) PROJECT UPDATE.—By not later than December 1, 2007, the Secretary shall submit to Congress a report on the details of such projects (including the project improvements towards quality and efficiency described in subsection (b)(2)(B)).

“(3) QUALITY IMPROVEMENT AND SAVINGS.—By not later than March 31, 2011, the Secretary shall submit to Congress a report on quality improvement and savings achieved as a result of the qualified gainsharing demonstration program established under subsection (a).

“(4) FINAL REPORT.—By not later than March 31, 2013, the Secretary shall submit to Congress a final report on the information described in paragraph (3).

“(1) FUNDING.—

“(1) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary for fiscal year 2006 $6,000,000, and for fiscal year 2010, $1,600,000, to carry out this section.

“(2) AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available for expenditure through fiscal year 2014 or until expended.

“(2) DEFINITIONS.—For purposes of this section:

“(1) DEMONSTRATION PROJECT.—The term ‘demonstration project’ means a project implemented under the qualified gainsharing demonstration program established under subsection (a).

“(2) HOSPITAL.—The term ‘hospital’ means a hospital that receives payment under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)), and does not include a critical access hospital (as defined in section 1861(mm) of such Act (42 U.S.C. 1395x(mm))).

“(3) MEDICARE.—The term ‘Medicare’ means the programs under title XVIII of the Social Security Act (this subchapter).

“(4) PHYSICIAN.—The term ‘physician’ means, with respect to a demonstration project, a physician de-
such legislation and administrative action as the Secretary may be necessary for the definition of the demonstration program, the reasonable costs of providing such services; and

"(B) for discharges occurring in a subsequent cost reporting period under the demonstration program, the lesser of—

"(i) the reasonable costs of providing such services in the cost reporting period involved; or

"(ii) the target amount (as defined in paragraph (2)), applicable to the cost reporting period involved.

"(2) TARGET AMOUNT.—For purposes of paragraph (1)(B), the term 'target amount' means, with respect to a rural community hospital for a particular 12-month cost reporting period—

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"(A) in the case of the second such cost reporting period for which this subsection is in effect, the reasonable costs of providing such covered inpatient hospital services as determined under paragraph (1)(A), and

"(B) in the case of a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase (under clause (i) of section 1886(b)(3)(B) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)) in the market basket percentage increase (as defined in clause (ii) of such section) for that particular cost reporting period.

"(c) FUNDING.—

"(1) IN GENERAL.—The Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42 U.S.C. 1395i) of such funds as are necessary for the costs of carrying out the demonstration program under this section.

"(2) BUDGET NEUTRALITY.—In conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented.

"(d) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

"(e) REPORT.—Not later than 6 months after the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

"(f) DEFINITIONS.—In this section:

"(1) RURAL COMMUNITY HOSPITAL DEFINED.—

"(A) IN GENERAL.—The term 'rural community hospital' means a hospital (as defined in section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e))) that—

"(i) is located in a rural area (as defined in section 1866(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))), or treated as being so located pursuant to section 1866(d)(8)(E) of such Act (42 U.S.C. 1395ww(d)(8)(E));

"(ii) subject to subparagraph (B), has fewer than 51 acute care inpatient beds, as reported in its most recent cost report;

"(iii) makes available 24-hour emergency care services; and

"(iv) is not eligible for designation, or has not been designated, as a critical access hospital under section 1820 (probably means section 1820 of the Social Security Act which is classified to section 1395f–4 of this title).

"(B) TREATMENT OF PSYCHIATRIC AND REHABILITATION UNITS.—For purposes of subparagraph (A)(ii), beds in a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital shall not be counted.

"(2) COVERED INPATIENT HOSPITAL SERVICES.—The term 'covered inpatient hospital services' means inpatient hospital services, and includes extended care services furnished under an agreement under section 1883 of the Social Security Act (42 U.S.C. 1395tt)."

"(g) FIVE-YEAR EXTENSION OF DEMONSTRATION PROGRAM.—

"(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, the Secretary shall conduct the demonstration program under this section for an additional 5-year period (in this section referred to as the '5-year extension period') that begins on the date immediately following the last day of the initial 5-year period under subsection (a)(5).

"(2) EXPANSION OF DEMONSTRATION STATES.—Notwithstanding subsection (a)(2), during the 5-year extension period, the Secretary shall expand the number of States with low population densities determined by the Secretary under such subsection to 20.

"(3) INCREASE IN MAXIMUM NUMBER OF HOSPITALS PARTICIPATING IN THE DEMONSTRATION PROGRAM.—Notwithstanding subsection (a)(4), during the 5-year extension period, not more than 30 rural community hospitals may participate in the demonstration program under this section.

"(4) HOSPITALS IN DEMONSTRATION PROGRAM ON DATE OF ENACTMENT.—In the case of a rural community hospital that is participating in the demonstration program under this section as of the last day of the initial 5-year period, the Secretary—

"(A) shall provide for the continued participation of such rural community hospital in the demonstration program during the 5-year extension period unless the rural community hospital makes an election, in such form and manner as the Secretary may specify, to discontinue such participation; and

"(B) in calculating the amount of payment under subsection (b) to the rural community hospital for covered inpatient hospital services furnished by the hospital during such 5-year extension period, shall substitute, under paragraph (1)(A) of such subsection—

"(i) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the first day of the 5-year extension period, for

"(ii) the reasonable costs of providing such services for discharges occurring in the first cost reporting period beginning on or after the implementation of the demonstration program."
"(a) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study to determine the impact of sections 401 through 406, 411, 415, and 505 [amending this title and parts J and L of title XVIII of the Social Security Act (42 U.S.C. 1395l, 1395m, 1395w, 1395x, 1395cc, and 1395tt) of this title and enacting provisions set out as notes under sections 1395f, 1395i, 1395i–4, 1395j, 1395m, and 1395w of this title]. The Commission shall analyze the data on total payments, growth in costs, capital spending, and other payment effects under those sections.

"(b) REPORTS.—

"(1) INTERIM REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003], the Commission shall submit to Congress an interim report on the matters studied under subsection (a) with respect only to changes to the critical access hospital provisions under section 405 [amending sections 1395f, 1395g, 1395i–4, 1395m, and 1395tt of this title and enacting provisions set out as notes under sections 1395f, 1395j, 1395i–4, and 1395w of this title].

"(2) FINAL REPORT.—Not later than 3 years after the date of the enactment of this Act [Dec. 8, 2003], the Commission shall submit to Congress a final report on all matters studied under subsection (a).

GAO STUDY AND REPORT ON APPROPRIATENESS OF PAYMENTS UNDER THE PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES


"(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine:

"(A) the appropriate level and distribution of payments in relation to costs under the prospective payment system under section 1886 of the Social Security Act (42 U.S.C. 1395ww) for inpatient hospital services furnished by subsection (d) hospitals (as defined in subsection (d)(1)(B) of such section); and

"(B) whether there is a need to adjust such payments under such system to reflect legitimate differences in costs across different geographic areas, kinds of hospitals, and types of cases.

"(2) REPORT.—Not later than 24 months after the date of the enactment of this Act [Dec. 8, 2003], the Comptroller General of the United States shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislative and administrative action as the Comptroller General determines appropriate.

NOT BUDGET NEUTRAL

Pub. L. 108–173, title V, § 503(d)(2), Dec. 8, 2003, 117 Stat. 2292, provided that: "There shall be no reduction or other adjustment in payments under section 1886 of the Social Security Act [subsec. (d) of this section] because an additional payment is provided under subsection (d)(5)(K)(i)(III) of such section.

ONE-TIME APPEALS PROCESS FOR HOSPITAL WAGE INDEX CLASSIFICATION


"(a) ESTABLISHMENT OF PROCESS.—

"(1) IN GENERAL.—The Secretary of Health and Human Services shall establish not later than January 1, 2004, by instruction or otherwise a process under which a hospital may appeal the wage index classification otherwise applicable to the hospital and select another area within the State (or, at the discretion of the Secretary, within a contiguous State) to which to be reclassified.

"(2) PROCESS REQUIREMENTS.—The process established under paragraph (1) shall be consistent with the following:

"(A) Such an appeal may be filed as soon as possible after the date of the enactment of this Act [Dec. 8, 2003] but shall be filed by no later than February 15, 2004.

"(B) Such an appeal shall be heard by the Medicare Geographic Reclassification Review Board.

"(C) There shall be no further administrative or judicial review of a decision of such Board.

"(3) RECLASSIFICATION UPON SUCCESSFUL APPEAL.—If the Medicare Geographic Reclassification Review Board determines that the hospital is a qualifying hospital (as defined in subsection (c)), the hospital shall be reclassified to the area selected under paragraph (1). Such reclassification shall apply with respect to discharges occurring during the 3-year period beginning with April 1, 2004.

"(4) INAPPLICABILITY OF CERTAIN PROVISIONS.—Except as the Secretary may provide, the provisions of paragraphs (8) and (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) shall not apply to an appeal under this section.

"(b) APPLICATION OF RECLASSIFICATION.—In the case of an appeal decided in favor of a qualifying hospital under subsection (a), the wage index reclassification shall not affect the wage index computation for any area or for any other hospital and shall not be effected in a budget neutral manner. The provisions of this section shall not affect payment for discharges occurring after the end of the 3-year-period referred to in subsection (a).

"(c) QUALIFYING HOSPITAL DEFINED.—For purposes of this section, the term 'qualifying hospital' means a hospital selected under subsection (b) that—

"(1) does not qualify for a change in wage index classification under paragraph (b) or (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) that—

"(I) does not qualify for a change in wage index classification under paragraph (b) or (10) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) on the basis of requirements relating to distance or commuting; and

"(II) meets such other criteria, as such as quality, as the Secretary may specify by instruction or otherwise.

The Secretary may modify the wage comparison guidelines promulgated under section 1886(d)(10)(D) of such Act (42 U.S.C. 1395ww(d)(10)(D)) in carrying out this section.

"(d) WAGE INDEX CLASSIFICATION.—For purposes of this section, the term 'wage index classification' means the geographic area in which it is classified for purposes of determining for a fiscal year the factor used to adjust the DRG prospective payment rate under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E) of such section.

"(e) LIMITATION ON EXPENDITURES.—The amount of additional expenditures resulting from the application of this section shall not exceed $900,000,000.

"(f) TRANSITIONAL EXTENSION.—Any reclassification of a county or other area made by Act of Congress for purposes of making payments under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) that expired on September 30, 2003, shall be deemed to be in effect during the period beginning on January 1, 2004, and ending on September 30, 2004.

"(g) DISREGARDING HOSPITAL RECLASSIFICATIONS FOR PURPOSES OF GROUP RECLASSIFICATIONS.—For purposes of the reclassification of a group of hospitals in a geographic area under section 1886(d) of the Social Security Act [subsec. (d) of this section] for purposes of discharges occurring beginning on October 1, 2007, and ending on the last date of the extension of reclassifications under section 106(a) of the Medicare Improvement[s] and Extension Act of 2006 (division B of Public Law 109–432) [set out above], a hospital reclassified under this section shall be deemed to be in effect during the period beginning on January 1, 2004, and ending on September 30, 2004.

"(h) DISREGARDING HOSPITAL RECLASSIFICATIONS FOR PURPOSES OF GROUP RECLASSIFICATIONS.—For purposes of the reclassification of a group of hospitals in a geographic area under section 1886(d) of the Social Security Act [subsec. (d) of this section] for purposes of discharges occurring beginning on October 1, 2007, and ending on the last date of the extension of reclassifications under section 106(a) of the Medicare Improvement[s] and Extension Act of 2006 (division B of Public Law 109–432) [set out above], a hospital reclassified under this section shall be deemed to be in effect during the period beginning on January 1, 2004, and ending on September 30, 2004.
EXCEPTION TO INITIAL RESIDENCY PERIOD FOR GERIATRIC RESIDENCY OR FELLOWSHIP PROGRAMS


"(a) CLARIFICATION OF CONGRESSIONAL INTENT.—Congress intended section 1886(h)(5)(F)(1) of the Social Security Act (42 U.S.C. 1395ww(h)(5)(F)(1)), as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99–272), to provide an exception to the initial residency period for geriatric residency or fellowship programs such that, where a particular approved geriatric training program requires a resident to complete 2 years of training to initially become board eligible in the geriatric specialty, the 2 years spent in the geriatric training program are treated as part of the resident's initial residency period, but are not counted against any limitation on the initial residency period.

"(b) INTERIM FINAL REGULATORY AUTHORITY AND EFFECTIVE DATE.—The Secretary [of Health and Human Services] shall promulgate interim final regulations consistent with the congressional intent expressed in this section after notice and pending opportunity for public comment to be effective for cost reporting periods beginning on or after October 1, 2003."

TREATMENT OF VOLUNTEER SUPERVISION


"(a) MORATORIUM ON CHANGES IN TREATMENT.—During the 1-year period beginning on January 1, 2004, for purposes of applying subsections (d)(6)(B) and (h) of section 1886 of the Social Security Act (42 U.S.C. 1395ww), the Secretary [of Health and Human Services] shall allow all hospitals to count residents in osteopathic and allopathic family practice programs in existence as of January 1, 2002, who are training at non-hospital sites, without regard to the financial arrangement between the hospital and the teaching physician practicing in the non-hospital site to which the resident has been assigned.

"(b) STUDY AND REPORT.—

"(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the appropriateness of alternative payment methodologies under such sections for the costs of training residents in non-hospital settings.

"(2) REPORT.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.

FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA

Pub. L. 108–173, title IX, §951, Dec. 8, 2003, 117 Stat. 2427, provided that: "Beginning not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall arrange to furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days used in computing the disproportionate patient percentage under such section for that hospital for the current cost reporting year. Such data shall also be furnished to other hospitals which would qualify for additional payments under part A of title XVIII of the Social Security Act [part A of this subchapter] on the basis of such data."

SPECIAL RULES FOR PAYMENT FOR FISCAL YEAR 2001

Pub. L. 106–554, §1(a)(6) [title III, §301(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–491, provided that: "Notwithstanding the amendment made by subsection (a) [amending this section] for purposes of making payments for fiscal year 2001 for inpatient hospital services furnished by subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))), the 'applicable percentage increase' referred to in section 1886(b)(3)(B)(i) of such Act (42 U.S.C. 1395ww(b)(3)(B)(i))—

"(1) for discharges occurring on or after October 1, 2000, and before April 1, 2001, shall be determined in accordance with subparagraph (XVI) of such section as in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

"(2) for discharges occurring on or after April 1, 2001, and before October 1, 2001, shall be equal to—

"(a) the market basket percentage increase plus 1.1 percentage points for hospitals (other than sole community hospitals) in all areas; and

"(B) the market basket percentage increase for sole community hospitals.''

Pub. L. 106–554, §1(a)(6) [title III, §302(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–493, provided that: "Notwithstanding paragraph (5)(B)(ii)(V) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(ii)(V)), for purposes of making payments for subsection (d) hospitals (as defined in paragraph (1)(B) of such section) with indirect costs of medical education, the indirect teaching adjustment factor referred to in paragraph (5)(B)(ii) of such section shall be determined, for discharges occurring on or after April 1, 2001, and before October 1, 2001, as if 'c' in paragraph (5)(B)(ii)(V) of such section equalled 1.66 rather than 1.54.''

Pub. L. 106–554, §1(a)(6) [title III, §303(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–493, provided that: "Notwithstanding the amendment made by subsection (a)(1) [amending this section], for purposes of making disproportionate share payments for subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) for fiscal year 2001, the additional payment amount otherwise determined under clause (ii) of section 1886(d)(5)(F) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F))—

"(1) for discharges occurring on or after October 1, 2000, and before April 1, 2001, shall be adjusted as provided by clause (ix)(III) of such section as in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

"(2) for discharges occurring on or after April 1, 2001, and before October 1, 2001, shall, instead of being reduced by 3 percent as provided by clause (ix)(III) of such section as in effect after the date of the enactment of this Act, be reduced by 1 percent.''

Pub. L. 106–554, §1(a)(6) [title V, §547(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–553, provided that:

"(a) INPATIENT HOSPITAL SERVICES.—The payment increase provided under the following sections shall not apply to discharges occurring after fiscal year 2001 and shall not be taken into account in calculating the payment amounts applicable for discharges occurring after such fiscal year:

"(1) Section 301(b)(2)(A) [set out as a note above] (relating to acute care hospital payment update),

"(2) Section 302(b) [set out as a note above] (relating to IME percentage adjustment),

"(3) Section 303(b)(2) [set out as a note above] (relating to DSH payments)."

CONSIDERATION OF PRICE OF BLOOD AND BLOOD PRODUCTS IN MARKET BASKET INDEX

Pub. L. 106–554, §1(a)(6) [title III, §301(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–491, provided that: "The Secretary of Health and Human Services shall, when next (after the date of the enactment of this Act [Dec. 21, 2000]) rebasing and revising the hospital market basket index (as defined in section 1886(b)(3)(B)(i)(I) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(i)(I))), consider the prices of blood and blood products purchased by hospitals and determine whether those prices are adequately reflected in such index."

MEDPAC STUDY AND REPORT REGARDING CERTAIN HOSPITAL COSTS

Pub. L. 106–554, §1(a)(6) [title III, §301(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–491, provided that:
Such process shall be established by October 1, 2001, for 1886(d)(3)(E) of such Act (42 U.S.C. 1395ww(d)(3)(E)).

Human Services shall establish a process (based on the putting and applying the area wage index under section treated as a single geographic area for purposes of computing and applying the area wage index under section 1886(d)(3)(E)) of such Act (42 U.S.C. 1395ww(d)(3)(E)).

''(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on—

(A) any increased costs incurred by subsection (d) hospitals (as defined in paragraph (1)(B) of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d))) in providing inpatient hospital services to Medicare beneficiaries under title XVIII of such Act (this subchapter); during the period beginning on October 1, 1983, and ending on September 30, 1999, that were attributable to—

(i) complying with new blood safety measure requirements; and

(ii) providing such services using new technologies;

(B) the extent to which the prospective payment system for such services under such section provides adequate and timely recognition of such increased costs;

(C) the prospects for (and to the extent practicable, the magnitude of) cost increases that hospitals will incur in providing such services that are attributable to complying with new blood safety measure requirements and providing such services using new technologies during the 10 years after the date of the enactment of this Act (Dec. 21, 2000); and

(D) the feasibility and advisability of establishing mechanisms under such payment system to provide for more timely and accurate recognition of such cost increases in the future.

''(2) CONSULTATION.—In conducting the study under this subsection, the Commission shall consult with representatives of the blood community, including—

(A) hospitals;

(B) organizations involved in the collection, processing, and delivery of blood; and

(C) organizations involved in the development of new blood safety technologies.

''(3) REPORT.—Not later than 1 year 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 paragraph (1) together with such recommendations for legislation and administrative action as the Commission determines appropriate.

PROCEDURE TO PERMIT STATEWIDE WAGE INDEX CALCULATION AND APPLICATION


``(1) IN GENERAL.—The Secretary of Health and Human Services shall establish a process (based on the voluntary process utilized by the Secretary of Health and Human Services under section 1448 of the Social Security Act (42 U.S.C. 1395w–4) for purposes of computing and applying a statewide geographic adjustment factor) under which an appropriate statewide entity may apply to have all the geographic areas in a State treated as a single geographic area for purposes of computing and applying the area wage index under section 1886(d)(3)(E) of such Act (42 U.S.C. 1395ww(d)(3)(E)). Such process shall be established by October 1, 2001, for reclassifications beginning in fiscal year 2003.

``(2) PROHIBITION ON INDIVIDUAL HOSPITAL RECLASSIFICATION.—Notwithstanding any other provision of law, if the Secretary applies a statewide geographic wage index under paragraph (1) with respect to a State, any application submitted by a hospital in that State under section 1886(d)(10) of the Social Security Act (42 U.S.C. 1395ww(d)(10)) for geographic reclassification shall not be considered."

COLLECTION OF INFORMATION ON OCCUPATIONAL MIX


``(1) COLLECTION OF INFORMATION.—The Secretary of Health and Human Services shall provide for the collection of data every 3 years on occupational mix for employees of each subsection (d) hospital (as defined in section 1886(d)(1)) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(D))) in the provision of inpatient hospital services, in order to construct an occupational mix adjustment in the hospital area wage index applied under section 1886(d)(3)(E) of such Act (42 U.S.C. 1395ww(d)(3)(E)).''

Pub. L. 106–554, §1(a)(6) [title III, §304(c)(3)], Dec. 21, 2000, 114 Stat. 2763, 2763A–495, provided that:—

``(B) the measurement under the third sentence of section 1886(d)(3)(E) [subsection (d)(3)(E) of this section], as amended by paragraph (2)."

PAYMENT FOR INPATIENT SERVICES OF PSYCHIATRIC HOSPITALS


``With respect to hospitals described in clause (i) of section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) and psychiatric units described in the matter following clause (v) of such section, in making incentive payments to such hospitals under section 1886(b)(1)(A) of such Act (42 U.S.C. 1395ww(b)(1)(A)) for cost reporting periods beginning on or after October 1, 2000, and before October 1, 2001, the Secretary of Health and Human Services, in clause (ii) of such section, shall substitute '3 percent' for '2 percent'."

EXPANDING RECOGNITION OF NEW TECHNOLOGIES INTO INPATIENT PPS CODING SYSTEM

Pub. L. 106–554, §1(a)(6) [title V, §535(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–548, provided that:—

``(1) REPORT.—Not later than April 1, 2001, the Secretary of Health and Human Services shall submit to Congress a report on methods of expeditiously incorporating new medical services and technologies into the clinical coding system used with respect to payment for inpatient hospital services furnished under the medicare program under title XVIII of the Social Security Act [this subchapter], together with a detailed description of the Secretary's preferred methods to achieve this purpose.

``(2) IMPLEMENTATION.—Not later than October 1, 2001, the Secretary shall implement the preferred methods described in the report transmitted pursuant to paragraph (1).''

CONSULTATION PRIOR TO RULEMAKING


``The Secretary of Health and Human Services shall consult with groups representing hospitals, physicians, and manufacturers of new medical technologies before publishing the notice of proposed rulemaking required by section 1886(d)(5)(K)(i) of the Social Security Act [subsection (d)(5)(K)(i) of this section] (as added by paragraph (1))."

SPECIAL PAYMENTS TO MAINTAIN 6.5 PERCENT MEDICARE PAYMENT FOR FISCAL YEAR 2000


``(1) ADDITIONAL PAYMENT.—In addition to payments made to each subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) under section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B))) which receives payment for the direct costs of medical education for discharges occurring in fiscal year 2000, the Secretary of Health and Human Services shall make one or more payments to each such hospital in an amount which, as estimated by the Secretary, is equal in the aggregate to the difference between the amount of payments to the hospital under such section for such discharges and the amount of payments that would have been paid under such section for such discharges if 'c' in clause (i)(IV) of such section equaled 1.5 rather than 1.47. Additional payments made under this subsection shall be made applying the same structure as applies to payments made under section 1886(d)(5)(B) of such Act.
PER DISCHARGE PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS


"(1) MODIFICATION OF REQUIREMENT.—In developing the prospective payment system for payment for inpatient hospital services provided in long-term care hospitals described in section 1886(d)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)(iv)) under the medicare program, such system shall include an adequate patient classification system that reflects the differences in patient resource use and costs, and shall maintain budget neutrality.

"(2) DEFAULT IMPLEMENTATION OF SYSTEM BASED ON EXISTING DRG METHODOLOGY.—If the Secretary is unable to implement the prospective payment system under section 123 of the BBRA by October 1, 2002, the Secretary shall implement a prospective payment system under such a system developed under subsection (a)(1)."

PER DIEM PROSPECTIVE PAYMENT SYSTEM FOR PSYCHIATRIC HOSPITALS


"(1) IN GENERAL.—The Secretary of Health and Human Services shall develop a per diem prospective payment system for payment for inpatient hospital services of psychiatric hospitals and units (as defined in paragraph (3)) under the medicare program. Such system shall include an adequate patient classification system that reflects the differences in patient resource use and costs, and shall maintain budget neutrality.

"(2) DEFINITION.—In this section, the term ‘psychiatric hospitals and units’ means a psychiatric hospital and units described in clause (i) of section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) and psychiatric units described in the matter following clause (v) of such section."

"(3) STUDY.—The Secretary of Health and Human Services shall conduct a study of the impact on utilization and beneficiary access to services of the implementation of the medicare prospective payment system for inpatient hospital services or rehabilitation facilities under section 1886(j) of the Social Security Act (42 U.S.C. 1395ww(j))."
“(2) REPORT.—Not later than 3 years after the date such system is first implemented, the Secretary shall submit to Congress a report on such study.”

MEDPAC STUDY ON MEDICARE PAYMENT FOR NON-PHYSICIAN HEALTH PROFESSIONAL CLINICAL TRAINING IN HOSPITALS


“(a) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study of medicare payment policy with respect to professional clinical training of different classes of nonphysician health care professionals (such as nurses, nurse practitioners, allied health professionals, physician assistants, and psychologists) and the basis for any differences in treatment among such classes.

“(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Nov. 29, 1999], the Commission shall submit a report to Congress on the study conducted under subsection (a).”

NOT COUNTING AGAINST NUMERICAL LIMITATION CERTAIN INTERNS AND RESIDENTS TRANSFERRED FROM A VA RESIDENCY PROGRAM THAT LOSES ACCREDITATION


“(a) IN GENERAL.—Any applicable resident described in paragraph (2) shall not be taken into account in applying any limitation regarding the number of residents or interns for which payment may be made under section 1886 of the Social Security Act (42 U.S.C. 1395ww).

“(2) APPLICABLE RESIDENT DESCRIBED.—An applicable resident described in this paragraph is a resident or intern who—

“(A) participated in graduate medical education at a facility of the Department of Veterans Affairs;

“(B) was subsequently transferred on or after January 1, 1997, and before July 31, 1998, to a hospital that was not a Department of Veterans Affairs facility; and

“(C) was transferred because the approved medical residency program in which the resident or intern participated would lose accreditation by the Accreditation Council on Graduate Medical Education if such program continued to train residents at the Department of Veterans Affairs facility.

“(3) EFFECTIVE DATE.—

“(A) IN GENERAL.—Paragraph (1) applies as if included in the enactment of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33].

“(B) RETROACTIVE PAYMENTS.—If the Secretary of Health and Human Services determines that a hospital operating an approved medical residency program is owed payments as a result of enactment of this subsection, the Secretary shall make such payments not later than 60 days after the date of the enactment of this Act [Nov. 29, 1999].”

GAO STUDY ON GEOGRAPHIC RECLASSIFICATION


“(a) IN GENERAL.—The Comptroller General of the United States shall conduct a study of medicare payment policy with respect to professional clinical training of different classes of nonphysician health care professionals (such as nurses, nurse practitioners, allied health professionals, physician assistants, and psychologists) and the basis for any differences in treatment among such classes.

“(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Nov. 29, 1999], the Comptroller General of the United States shall submit to Congress a report on the study conducted under subsection (a).”

CONTINUING TREATMENT OF PREVIOUSLY DESIGNATED CENTERS

Section 2302(b) of Pub. L. 105–33 provided that:

“(1) IN GENERAL.—Any hospital classified as a rural referral center by the Secretary of Health and Human Services under section 1886(d)(5)(C) of the Social Security Act [subsec. (d)(5)(C) of this section] for fiscal year 1998 shall be classified as such a rural referral center for fiscal year 1998 and each subsequent fiscal year.

“(2) BUDGET NEUTRALITY.—The provisions of section 1886(d)(8)(D) of the Social Security Act [subsec. (d)(8)(D) of this section] shall apply to reclassifications made pursuant to paragraph (1) in the same manner as such provisions apply to a reclassification under section 1886(d)(10) of such Act [subsec. (d)(10) of this section].”

HOSPITAL GEOGRAPHIC RECLASSIFICATION PERMITTED FOR PURPOSES OF DISPROPORTIONATE SHARE PAYMENT ADJUSTMENTS

Section 2302(b) of Pub. L. 105–33 provided that:

“(a) IN GENERAL.—For the period described in subsection (c), the Medicare Geographic Classification Review Board shall consider the application under section 1886(d)(10)(S)(i) of the Social Security Act (42 U.S.C. 1395ww(d)(10)(S)(i)) of a hospital described in 1886(d)(1)(B) of such Act (42 U.S.C. 1395ww(d)(1)(B)) to change the hospital’s geographic classification for purposes of determining for a fiscal year eligibility for and amount of additional payment amounts under section 1886(d)(5)(F) of such Act (42 U.S.C. 1395ww(d)(5)(F)).

“(b) APPLICABLE GUIDELINES.—The Medicare Geographic Classification Review Board shall apply the guidelines established for reclassification under subsection (c) of section 1886(d)(10)(S)(i) of such Act to reclassification by reason of subsection (d) of section 1886(d)(10)(S)(i) of such Act to reclassification by reason of subsection (c) of section 1886(d)(10)(S)(i) of such Act.

“(c) PERIOD DESCRIBED.—The period described in this subsection is the period beginning on the date of the enactment of this Act [Aug. 5, 1997] and ending 30 months after such date.”

TEMPORARY RELIEF FOR CERTAIN NON-TEACHING, NON-DSH HOSPITALS


“(1) IN GENERAL.—In the case of a hospital described in paragraph (2) for its cost reporting period—

“(A) beginning in fiscal year 1998 the amount of payment made to the hospital under section 1886(d) of the Social Security Act [subsec. (d) of this section] for discharges occurring during such fiscal year only shall be increased as though the applicable percentage increase (otherwise applicable to discharges occurring during fiscal year 1998 under section 1886(b)(3)(B)(I)(XIII) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(I)(XIII))) had been increased by 0.5 percentage points; and

“(B) beginning in fiscal year 1999 the amount of payment made to the hospital under section 1886(d) of...
the Social Security Act for discharges occurring during such fiscal year only shall be increased as though the applicable percentage increase (otherwise applicable to discharges occurring during fiscal year 1999 under section 1886(b)(3)(B)(i)(XIV) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(i)(XIV))) had been increased by 0.3 percentage points.

Subparagraph (A) shall not apply in computing the increase under subparagraph (B) and neither subparagraph shall affect payment for discharges for any hospital occurring during a fiscal year after fiscal year 1999. Payment increases under this subsection for discharges occurring during a fiscal year are subject to settlement after the close of the fiscal year.

(2) HOSPITALS COVERED.—A hospital described in this paragraph for a cost reporting period is a hospital—

(A) that is described in paragraph (3) for such period;

(B) that is located in a State in which the amount of the aggregate payments under section 1886(d) of such Act [subsec. (d) of this section] for hospitals located in the State and described in paragraph (3) for their cost reporting periods beginning during fiscal year 1995 is less than the allowable operating costs of inpatient hospital services (as defined in section 1886(a)(4) of such Act) for all such hospitals in that State with respect to such cost reporting periods; and

(C) with respect to which the payments under section 1886(d) of such Act (42 U.S.C. 1395ww(d)) for discharges occurring in the cost reporting period involved, as estimated by the Secretary, is less than the allowable operating costs of inpatient hospital services (as defined in section 1886(a)(4) of such Act (42 U.S.C. 1395ww(a)(4)(A)) for such hospital for such period, as estimated by the Secretary.

(3) NON-TEACHING, NON-DSH HOSPITALS DESCRIBED.—A hospital described in this paragraph for a cost reporting period is a subsection (d) hospital (as defined in section 1886(d)(1)(B)) of such Act (42 U.S.C. 1395ww(d)(1)(B)) that—

(A) is not receiving any additional payment amount described in section 1886(d)(5)(F) of such Act (42 U.S.C. 1395ww(d)(5)(F)) for discharges occurring during the period;

(B) is not receiving any additional payment under section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B)) or a payment under section 1886(b)(5) of such Act (42 U.S.C. 1395ww(b)(5)) for discharges occurring during the period; and

(C) does not qualify for payment under section 1886(d)(5)(G) of such Act (42 U.S.C. 1395ww(d)(5)(G)) for the period.

FORMULA FOR ADDITIONAL PAYMENT AMOUNTS; REPORT
Section 4409 of Pub. L. 105–33 provided that:

(a) NEW GUIDELINES FOR RECLASSIFICATION.—Notwithstanding the guidelines published under section 1886(d)(10)(D)(i)(I) of the Social Security Act (42 U.S.C. 1395ww(d)(10)(D)(i)(I)), the Secretary of Health and Human Services shall publish alternative guidelines under which a hospital described in subsection (b) qualifies for geographic reclassification under such section for a fiscal year beginning with fiscal year 1998.

(b) HOSPITALS COVERED.—A hospital described in this subsection is a hospital that demonstrates that—

(1) the average hourly wage paid by the hospital is not less than 108 percent of the average hourly wage paid by all other hospitals located in the Metropolitan Statistical Area (or the New England County Metropolitan Area) in which the hospital is located; and

(2) at least 25 percent of the hospital's labor costs are attributable to wages paid by all hospitals located in such Area.

(ii) The hospital submitted an application requesting reclassification for purposes of wage index under section 1886(d)(10)(C) of such Act (42 U.S.C. 1395ww(d)(10)(C)) in each of fiscal years 1992 through 1997 and that such request was approved for each of such fiscal years.

FLOOR ON AREA WAGE INDEX
Section 4410 of Pub. L. 105–33 provided that:

(a) IN GENERAL.—For purposes of section 1886(d)(3)(E) of the Social Security Act (42 U.S.C. 1395ww(d)(3)(E)) for discharges occurring on or after October 1, 1997, the area wage index applicable under such section to any hospital which is not located in a rural area (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) may not be less than the area wage index applicable under such section to hospitals located in rural areas in the State in which the hospital is located.

(b) IMPLEMENTATION.—The Secretary of Health and Human Services shall adjust the area wage index referred to in subsection (a) for hospitals not described in such subsection in a manner which assures that the aggregate payments made under section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)) in a fiscal year for the operating costs of inpatient hospital services are not greater or less than those which would have been made in the year if this section did not apply.
"(c) Exclusion of Certain Wages.—In the case of a hospital that is owned by a municipality and that was reclassified as an urban hospital under section 1866(d)(10) of the Social Security Act [subsection (d)(10) of this section] for fiscal year 1996, in calculating the hospital's average hourly wage for purposes of geographic reclassification under such section for fiscal year 1996, the Secretary of Health and Human Services shall exclude the general service wages and hours of personnel associated with a skilled nursing facility that is owned by the same municipality and that is physically separated from the hospital to the extent that such wages and hours of such personnel are not shared with the hospital and are separately documented. A hospital that applied for and was denied reclassification as an urban hospital for fiscal year 1996, but that would have received reclassification had the exclusion required by this section been applied to it, shall be reclassified as an urban hospital for fiscal year 1996.


Section 4415(d) of Pub. L. 106-33 provided that: "Not later than October 1, 1999, the Secretary of Health and Human Services shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report that describes the effect of the amendments to section 1866(b)(1) of the Social Security Act (42 U.S.C. 1395ww(b)(1)), made under this section, on psychiatric hospitals (as defined in section 1866(d)(1)(B)(i) of such Act (42 U.S.C. 1395ww(d)(1)(B)(i)) that have approved medical residency training programs under title XVIII of such Act (42 U.S.C. 1395 et seq.)."

TREATMENT OF CERTAIN CANCER HOSPITALS; PAYMENT

Pub. L. 106-554, §1(a)(4) [div. B, title I, §152(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A-252, provided that:

"(1) Application to cost reporting periods.—Any classification by reason of section 1866(d)(1)(B)(v)(III) of the Social Security Act [subsection (d)(1)(B)(v)(III) of this section] (as added by subsection (a)) shall apply to 12-month cost reporting periods beginning on or after July 1, 1999.

"(2) Base year.—Notwithstanding the provisions of section 1866(b)(3)(E) of such Act (42 U.S.C. 1395ww(b)(3)(E)) or other provisions to the contrary, the base cost reporting period for purposes of determining the target amount for any hospital classified by reason of section 1866(d)(1)(B)(v)(III) of such Act ( subsection (d)(1)(B)(v)(III) of this section) (as added by subsection (a)) shall apply to 12-month cost reporting periods beginning on or after July 1, 1999.

"(3) Deadline for payments.—Any payments owed to a hospital by reason of this subsection shall be made expeditiously, but in no event later than 1 year after the date of enactment of this Act [Aug. 5, 1997]."

Report on Exceptions

Section 4415(b) of Pub. L. 106-33 provided that: "The Secretary of Health and Human Services shall publish annually in the Federal Register a report describing the total amount of payments attributable to hospitals by reason of section 1866(b)(4) of the Social Security Act (42 U.S.C. 1395ww(b)(4)), as amended by subsection (a), ending during the previous fiscal year."

Development of Proposal on Payments for Long-Term Care Hospitals

Section 4422 of Pub. L. 106-33 provided that:

"(a) In General.—

"(1) Legislative Proposal.—The Secretary of Health and Human Services shall develop a legislative proposal for establishing a case-mix adjusted prospective payment system for payment of long-term care hospitals described in section 1866(d)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)(iv)) under the medicare program. Such system shall include an adequate patient classification system that reflects the differences in patient resource use and costs among such hospitals.

"(2) Collection of Data and Evaluation.—In developing the legislative proposal described in paragraph (1), the Secretary—

"(A) may require such long-term care hospitals to submit such information to the Secretary as the Secretary may require to develop the proposal; and

"(B) shall consider several payment methodologies, including the feasibility of expanding the current diagnosis-related groups and prospective payment system established under section 1866(d) of the Social Security Act [subsection (d) of this section] to apply to payments under the medicare program to long-term care hospitals.

"(b) Report.—Not later than October 1, 1999, the Secretary shall submit to the appropriate committees of Congress a report that includes the legislative proposal developed under subsection (a)(1)."

Dissemination of Information on High Per Discharge Relative Values for In-Hospital Physicians' Services

Section 4506 of title IV of Pub. L. 106-33 provided that:

"(a) Determination and Notice Concerning Hospital-Specific Per Discharge Relative Values.—

"(1) In General.—For 1999 and 2001 the Secretary of Health and Human Services shall determine for each hospital—

"(A) the hospital-specific per discharge relative value under subsection (b); and

"(B) whether the hospital-specific relative value is projected to be excessive (as determined based on such value represented as a percentage of the median of hospital-specific per discharge relative values determined under subsection (b)).

"(2) Notice to subset of medical staffs; evaluation of responses.—The Secretary shall notify the medical executive committee of a subset of the hospitals identified under paragraph (1)(B) as having an excessive hospital-specific relative value, of the determinations made with respect to the medical staff under paragraph (1). The Secretary shall evaluate the responses of the hospitals so notified with the responses of other hospitals so identified that were not so notified.

"(b) Determination of Hospital-Specific Per Discharge Relative Values.—

"(1) In General.—For purposes of this section, the hospital-specific per discharge relative value for the medical staff of a hospital (other than a teaching hospital) for a year shall be equal to the average per discharge relative value (as determined under section 1848(c)(2) of the Social Security Act (42 U.S.C.
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1395w–4(c)(2)(A) for physicians’ services furnished to inpatients of the hospital by the hospital’s medical staff (excluding interns and residents) during the second year preceding that calendar year, adjusted for variations in case-mix among hospitals and disproportionate share status and teaching status among hospitals (as determined by the Secretary under paragraph (3))

“(2) SPECIAL RULE FOR TEACHING HOSPITALS.—The hospital-specific relative value projected for a teaching hospital in a year shall be equal to the sum of—

“(A) the average per discharge relative value (as determined under section 1886(d) of the Social Security Act (42 U.S.C. 1395x(a)(2))) for physicians’ services furnished to inpatients of the hospital by the hospital’s medical staff (excluding interns and residents) in the second year preceding that calendar year, and

“(B) the equivalent per discharge relative value (as determined under such section) for physicians’ services furnished to inpatients of the hospital by interns and residents of the hospital during the second year preceding that calendar year, adjusted for variations in case-mix among hospitals, and in disproportionate share status and teaching status among hospitals (as determined by the Secretary under paragraph (3)).

The Secretary shall determine the equivalent relative value unit per discharge for interns and residents of the hospital during the second year preceding that calendar year, adjusted for variations in case-mix among hospitals and in disproportionate share status and teaching status among hospitals (as determined by the Secretary under paragraph (3)).

“(3) ADJUSTMENT FOR TEACHING AND DISPROPORTIONATE SHARE HOSPITALS.—The Secretary shall adjust the allowable per discharge relative values otherwise determined under this subsection to take into account the needs of teaching hospitals and hospitals receiving additional payments under subparagraphs (F) and (G) of section 1886(d)(6) of the Social Security Act (42 U.S.C. 1395ww(d)(6)). The adjustment for teaching status or disproportionate share shall not be less than zero.

“(d) DEFINITIONS.—For purposes of this section:

“(1) HOSPITAL.—The term ‘hospital’ means a hospital which has a teaching program for the medical education of medical students and has one or more of the following entities:

“(A) a school of allopathic medicine or osteopathic medicine.

“(B) another teaching hospital, which may be a children’s hospital.

“(C) a Federally qualified health center.

“(D) a medical group practice.

“(E) a managed care entity.

“(F) an entity furnishing outpatient services.

“(G) such other entity as the Secretary determines to be appropriate.

“(2) MEDICAL STAFF.—An individual furnishing a physician’s service is considered to be on the medical staff of a hospital if

“(A) if (in accordance with requirements for hospitals established by the Joint Commission on Accreditation of Health Organizations)

“(i) the individual is subject to bylaws, rules, and regulations established by the hospital to provide a framework for the self-governance of medical staff activities,

“(ii) subject to the bylaws, rules, and regulations, the individual has clinical privileges granted by the hospital’s governing body, and

“(iii) under the clinical privileges, the individual may provide physicians’ services independently within the scope of the individual’s clinical privileges, or

“(B) if the physician provides at least one service to an individual entitled to benefits under this title in that hospital.

“(3) PHYSICIANS’ SERVICES.—The term ‘physicians’ services’ means the services described in section 1886(h)(3) of the Social Security Act (42 U.S.C. 1395ww(h)(3)).

“(4) RURAL AREA; URBAN AREA.—The terms ‘rural area’ and ‘urban area’ have the meaning given those terms under section 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D)).

“(5) SECRETARY.—The term ‘Secretary’ means the Secretary of Health and Human Services.

“(6) TEACHING HOSPITAL.—The term ‘teaching hospital’ means a hospital which has a teaching program approved as specified in section 1861(b)(6) of the Social Security Act (42 U.S.C. 1395b(b)(6)).

INCENTIVE PAYMENTS UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS; RELATION TO DEMONSTRATION PROJECTS AND AUTHORITY; REGULATIONS

Section 4626(b), (c) of Pub. L. 105–33 provided that:

“(b) RELATION TO DEMONSTRATION PROJECTS AND AUTHORITY.—

“(1) Section 1886(h)(6) of the Social Security Act (subsection (h)(6) of this section), added by subsection (a), other than subparagraph (F)(ii) thereof, shall not apply to any residency training program with respect to which a demonstration project described in paragraph (3) has been approved by the Health Care Financing Administration as of May 27, 1997.

“(2) Effective May 27, 1997, the Secretary of Health and Human Services is not authorized to approve any demonstration project described in paragraph (3) for any residency training year beginning before July 1, 2006.

“(3) A demonstration project described in this paragraph is a project that primarily provides for additional payments under section 1886(d) of the Social Security Act [this subchapter] in connection with a reduction in the number of residents in a medical residency training program.

“(c) INTERIM, FINAL REGULATIONS.—In order to carry out the amendment made by subsection (a) in a timely manner, the Secretary of Health and Human Services may first promulgate regulations, that take effect on an interim basis, after notice and pending opportunity for public comment, by not later than 6 months after the date of the enactment of this Act [Aug. 5, 1997].”

DEMONSTRATION PROJECT ON USE OF CONSORTIA

Section 4628 of Pub. L. 105–33 provided that:

“(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall establish a demonstration project under which, instead of making payments to teaching hospitals pursuant to section 1886(h) of the Social Security Act [subsection (h) of this section], the Secretary shall make payments under this section to each consortium that meets the requirements of subsection (b) and that applies to be included under the project.

“(b) QUALIFYING CONSORTIA.—For purposes of subsection (a), a consortium meets the requirements of this subsection if the consortium is in compliance with the following:

“(1) The consortium consists of a teaching hospital with one or more approved medical residency training programs and one or more of the following entities:

“(A) A school of allopathic medicine or osteopathic medicine.

“(B) Another teaching hospital, which may be a children’s hospital.

“(C) A Federally qualified health center.

“(D) A medical group practice.

“(E) A managed care entity.

“(F) An entity furnishing outpatient services.

“(G) Such other entity as the Secretary determines to be appropriate.

“(2) The members of the consortium have agreed to participate in the programs of graduate medical education that are operated by the entities in the consortium.

“(3) With respect to the receipt by the consortium of payments made pursuant to this section, the members of the consortium have agreed on a method for allocating the payments among the members.

“(4) The consortium meets such additional requirements as the Secretary may establish.

“(c) AMOUNT AND SOURCE OF PAYMENT.—The total of payments to a qualifying consortium for a fiscal year pursuant to subsection (a) shall not exceed the amount that would have been paid under section 1886(h) or (k)
of the Social Security Act (subsecs. (h), (k) of this section) for the teaching hospital (or hospitals) in the consortium. Such payments shall be made in such proportion as the Secretary determines after consultation with each of the true funds established under title XVIII of such Act (this subchapter) as the Secretary specifies.'"

RECOMMENDATIONS ON LONG-TERM POLICIES REGARDING TEACHING HOSPITALS AND GRADUATE MEDICAL EDUCATION

Section 4639 of Pub. L. 105–33 provided that:

"(a) IN GENERAL.—The Medicare Payment Advisory Commission (established under section 1805 of the Social Security Act [section 1395b–6 of this title] and in this section referred to as the 'Commission') shall examine and develop recommendations on whether and to what extent Medicare payment policies and other Federal policies regarding teaching hospitals and graduate medical education should be changed. Such recommendations shall include recommendations regarding each of the following:

"(1) Possible methodologies for making payments for graduate medical education and the selection of entities to receive such payments. Matters considered under this paragraph shall include—

"(A) issues regarding children's hospitals and approved medical residency training programs in pediatrics, and

"(B) whether and to what extent payments are being made (or should be made) for training in the nursing and other allied health professions.

"(2) Federal policies regarding international medical graduates.

"(3) The dependence of schools of medicine on service-generated income.

"(4) Whether and to what extent the needs of the United States regarding the supply of physicians, in the aggregate and in different specialties, will change during the 10-year period beginning on October 1, 1997, and whether and to what extent any such changes will have significant financial effects on teaching hospitals.

"(5) Methods for promoting an appropriate number, mix, and geographical distribution of health professionals.

"(b) CONSULTATION.—In conducting the study under subsection (a), the Commission shall consult with the Council on Graduate Medical Education and individuals with expertise in the area of graduate medical education, including—

"(1) deans from allopathic and osteopathic schools of medicine;

"(2) chief executive officers (or equivalent administrative heads) from academic health centers, integrated health care systems, approved medical residency training programs, and teaching hospitals that sponsor approved medical residency training programs;

"(3) chairs of departments or divisions from allopathic and osteopathic schools of medicine, schools of dentistry, and approved medical residency training programs in oral surgery;

"(4) individuals with leadership experience from representative fields of non-physician health professionals;

"(5) individuals with substantial experience in the study of issues regarding the composition of the health care workforce of the United States; and

"(6) individuals with expertise in health care payment policies.

"(c) REPORT.—Not later than 2 years after the date of the enactment of this Act [Aug. 5, 1997], the Commission shall submit to the Congress a report providing its recommendations under this section and the reasons and justifications for such recommendations.'"

STUDY OF HOSPITAL OVERHEAD AND SUPERVISORY PHYSICIAN COMPONENTS OF DIRECT MEDICAL EDUCATION COSTS

Section 4630 of Pub. L. 105–33 provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study with respect to—

"(1) variations among hospitals in the hospital overhead and supervisory physician components of their direct medical education costs taken into account under section 1886(h) of the Social Security Act [subsec. (h) of this section], and

"(2) the reasons for such variations.

"(b) REPORT.—Not later than 1 year after the date of the enactment of this Act [Aug. 5, 1997], the Secretary shall report the results of the study conducted under subsection (a) to the appropriate committees of Congress, including recommendations for legislation reducing variations described in subsection (a) that the Secretary finds inappropriate.'"
that:

"(A) notify such hospital of such failure to qualify, "(B) provide an opportunity for such hospital to
decline such reclassification, and
"(C) if the hospital—
"(i) declines such reclassification, administer the
Social Security Act [this chapter] (other than section
1886(d)(8)(D)) for such fiscal year as if the decision
by the Review Board had not occurred, or
(ii) fails to decline such reclassification, adminis-
ter the Social Security Act without regard to
paragraph (1).

"(3) REQUIRING LUMP-SUM RETROACTIVE PAYMENT FOR
HOSPITALS LOSING CLASSIFICATION

"(A) IN GENERAL.—In the case of a hospital de-
scribed in paragraph (1), the Secretary of Health and
Human Services shall make a lump-sum payment to
the hospital equal to the difference between the ag-
gregate payment made to the hospital under section
1886 of such Act (excluding outlier payments under
subsubsection (d)(5) of such section) during the period
of applicability described in subparagraph (B) and the
aggregate payment that would have been made to the
hospital under such section if, during the period of
applicability, the hospital was classified a regional
referral center under section 1886(d)(5)(C) of such Act.

"(B) PERIOD OF APPLICABILITY.—In subparagraph
(A), the 'period of applicability' is the period that
begins on October 1, 1992, and ends on the date of the
enactment of this Act [Aug. 10, 1993].

HOSPITALS DECLINING URBAN AREA RECLASSIFICATIONS:
RETROACTIVE PAYMENTS


"(1) PERMITTING HOSPITALS TO DECLINE RECLASSIFICA-
TION.—If any hospital fails to qualify as a medicare-de-
pendant, small rural hospital under section
1886(d)(5)(G)(1) of the Social Security Act (subsec.
d(5)(G)(1) of this section) as a result of a decision by
the Medicare Geographic Classification Review Board
under section 1886(d)(10) of such Act to reclassify the
hospital as being located in an urban area for fiscal
years 1994, the Secretary of Health and Human Serv-
ces shall—
"(A) notify such hospital of such failure to qualify,
"(B) provide an opportunity for such hospital to
decline such reclassification, and
"(C) if the hospital—
"(i) declines such reclassification, administer the
Social Security Act [this chapter] (other than section
1886(d)(8)(D)) for such fiscal year as if the decision
by the Review Board had not occurred, or
(ii) fails to decline such reclassification, administer
the Social Security Act without regard to
paragraph (1).

"(2) REQUIRING LUMP-SUM RETROACTIVE PAYMENT FOR
HOSPITALS LOSING CLASSIFICATION

"(A) IN GENERAL.—In the case of a hospital de-
scribed in paragraph (1), the Secretary of Health and
Human Services shall make a lump-sum payment to
the hospital equal to the difference between the ag-
gregate payment made to the hospital under section
1886 of such Act (excluding outlier payments under
subsubsection (d)(5)(A) of such section) during the period
of applicability described in subparagraph (B) and the
aggregate payment that would have been made to the
hospital under such section if, during the period of
applicability, the hospital was classified a regional
referral center under section 1886(d)(5)(C) of such Act.

"(B) PERIOD OF APPLICABILITY.—In subparagraph
(A), the 'period of applicability' is the period that
begins on October 1, 1992, and ends on the date of the
enactment of this Act [Aug. 10, 1993].

"(3) REQUIREMENTS OF APPLICABILITY.

"(A) IN GENERAL.—In the case of a hospital treated
as a medicare-dependent, small rural hospital under
section 1886(d)(5)(G) of the Social Security Act, the
Secretary of Health and Human Services shall make a
lump-sum payment to the hospital equal to the dif-
fERENCE between the aggregate payment made to the
hospital under section 1886 of such Act (excluding
outlier payments under subsection (d)(5) of such sec-
tion) during the period of applicability described in
subparagraph (B) and the aggregate payment that
would have been made to the hospital under such sec-
tion if, during the period of applicability, section
1886(d)(5)(G) of such Act had been applied as if the
amendments made by paragraph (1) [amending this
section] had been in effect.

"(3) REQUIREMENTS OF APPLICABILITY.

"(A) IN GENERAL.—In the case of a hospital treated
as a medicare-dependent, small rural hospital under
section 1886(d)(5)(G) of the Social Security Act, the
Secretary of Health and Human Services shall make a
lump-sum payment to the hospital equal to the dif-
fERENCE between the aggregate payment made to the
hospital under section 1886 of such Act (excluding
outlier payments under subsection (d)(5)(A) of such sec-
tion) during the period of applicability described in
subparagraph (B) and the aggregate payment that
would have been made to the hospital under such sec-
tion if, during the period of applicability, section
1886(d)(5)(G) of such Act had been applied as if the
amendments made by paragraph (1) [amending this
section] had been in effect.

"(B) PERIOD OF APPLICABILITY.—In subparagraph
(A), the 'period of applicability' is, with respect to a
hospital, the period that begins on the first day of the
hospital's first 12-month cost reporting period that
begins after April 1, 1992, and ends on the date of the
enactment of this Act [Aug. 10, 1993].

ADJUSTMENT IN GME BASE-YEAR COSTS OF FEDERAL
INSURANCE CONTRIBUTIONS ACT

Section 13363(d) of Pub. L. 103–66 provided that:

"(1) IN GENERAL.—In determining the amount of pay-
ment to be made under section 1886(h) of the Social Se-
curity Act [subsec. (h) of this section] in the case of a
hospital described in paragraph (2) for cost reporting
periods beginning on or after October 1, 1992, the Sec-
retary of Health and Human Services shall redetermine
the approved FTE resident amount to reflect the
amount that would have been paid the hospital if, dur-
ing the hospital's base cost reporting period, the hos-
pital had been liable for FICA taxes or for contribu-
tions to the retirement system of a State, a political
subdivision of a State, or an instrumentality of such a
State or political subdivision with respect to interns
and residents in its medical residency training pro-
gram.

"(2) HOSPITALS AFFECTED.—A hospital described in
this paragraph is a hospital that did not pay FICA
taxes with respect to interns and residents in its med-
cal residency training program during the hospital's
base cost reporting period, but is required to pay FICA
taxes or make contributions to a retirement system de-
scribed in paragraph (1) with respect to such interns
and residents because of the amendments made by sec-
tion 11332(b) of OBRA-1990 [Pub. L. 101–508, amending
section 3121 of Title 20, Internal Revenue Code].

"(3) DEFINITIONS.—In this subsection:

"(A) The 'base cost reporting period' for a hospital is
the hospital's cost reporting period that began dur-
ing fiscal year 1984.

"(B) The term 'FICA taxes' means, with respect to a
hospital, the taxes under section 3111 of the Inter-

DETERMINATION OF AREA WAGE INDEX FOR DISCHARGES
OCcurring JANUARY 1, 1991 TO OCTOBER 1, 1993

Section 4002(d)(1) of Pub. L. 101–508 provided that:

"(A) For purposes of section 1886(d)(3)(E) of the Social Security Act [subsec. (d)(3)(E) of this section] for dis-
charges occurring on or after January 1, 1991, and be-
fore October 1, 1993, the Secretary of Health and Human
Services shall apply an area wage index determined
using the survey of the 1988 wages and wage-related
costs of hospitals in the United States conducted under
such section.

"(B) The Secretary shall apply the wage index de-
scribed in subparagraph (A) without regard to a pre-
vious survey of wages and wage-related costs.

STUDY AND REPORT ON RELATIONSHIP BETWEEN NON-
WAGE-RELATED INPUT PRICES AND ADJUSTED AVER-
AGE STANDARDIZED AMOUNTS

Section 4002(e)(2) of Pub. L. 101–508 directed Secretary
of Health and Human Services to collect sufficient data
on the input prices associated with the non-wage-relat-
ed portion of the adjusted average standardized
amounts established under subsec. (d)(3) of this section
to identify extent to which variations in such amounts
among hospitals located in different geographic areas
are attributable to differences in such prices, and, not
later than June 1, 1993, submit a report to Congress
analyzing such data, with such report to include recom-
endations regarding a methodology for adjusting such
average standardized amounts to reflect such varia-
tions.

DEADLINE FOR SUBMISSION OF APPLICATIONS TO
geographic classification for fiscal year 1992 under section 1886(d)(10) of the Social Security Act [subsec. (d)(10) of this section] has met the
Payments for Medical Education Costs

Section 4004 of Pub. L. 101–508 provided that:
"(a) Hospital Graduate Medical Education Recoupment.

"(1) In General.—The Secretary of Health and Human Services may not, before October 1, 1991, recoup payments from a hospital because of alleged overpayments to such hospital under part A of title XVIII of the Social Security Act [part A of this subchapter] due to a determination that the amount of payments made for graduate medical education programs exceeds the amount allowable under section 1886(b)(1) [subsec. (b) of this section].

"(2) Cap on Annual Amount of Recoupment.—With respect to overpayments to a hospital described in paragraph (1), the Secretary may not recoup more than 25 percent of the amount of such overpayments from the hospital during a fiscal year.

"(3) Effective Date.—Paragraphs (1) and (2) shall take effect October 1, 1990.

"(b) University Hospital Nursing Education.

"(1) In General.—The reasonable costs incurred by a hospital (or by an educational institution related to the hospital by common ownership or control) during a cost reporting period for clinical training (as defined by the Secretary) conducted on the premises of the hospital under approved nursing and allied health education programs that are not operated by the hospital shall be allowable as reasonable costs under part A of title XVIII of the Social Security Act and reimbursed under such part on a pass-through basis.

"(2) Conditions for Reimbursement.—The reasonable costs incurred by a hospital during a cost reporting period that ended on or before October 1, 1989, and allowable under (b)(1) during the cost reporting period does not exceed the proportion of total allowable costs that is attributable to the clinical training costs during the cost reporting period described in subparagraph (A); and

"(C) the hospital receives a benefit for the support it furnishes to such program through the provisions of clinical services by nursing or allied health students participating in such program; and

"(D) the costs incurred by the hospital for such program do not exceed the costs that would be incurred by the hospital if it operated the program itself.

"(3) Prohibition Against Recoupment of Costs by Secretary.—

"(A) In General.—The Secretary of Health and Human Services may not recoup payments from (or otherwise reduce or adjust payments under part A of title XVIII of the Social Security Act) to a hospital because of alleged overpayments described in sub-paragraph (A), the Secretary shall refund the amount recouped, reduced, or adjusted from the hospital.

"(B) Refund of Amounts Recouped.—If, prior to the date of the enactment of this Act [Nov. 5, 1990], the Secretary has recouped payments from (or otherwise reduced or adjusted payments under part A of title XVIII of the Social Security Act) to a hospital because of alleged overpayments described in subparagraph (A), the Secretary shall refund the amount recouped, reduced, or adjusted from the hospital.

"(4) Special Audit to Determine Costs.—In determining the amount of costs incurred by, claimed by, and reimbursed to, a hospital for purposes of this subsection, the Secretary shall conduct a special audit (or use such other appropriate mechanism) to ensure the accuracy of such past claims and payments.

"(5) Effective Date.—Except as provided in paragraph (3), the provisions of this subsection shall apply to cost reporting periods beginning on or after October 1, 1990.
".

Section 4159 of Pub. L. 101–508 provided that:
"(a) Hospital Graduate Medical Education Recoupment.

"(1) In General.—The Secretary of Health and Human Services may not, before October 1, 1991, recoup payments from a hospital because of alleged overpayments to such hospital under part B of title XVIII of the Social Security Act [part B of this subchapter] due to a determination that the amount of payments made for graduate medical education programs exceeds the amount allowable under section 1886(b)(1) [subsec. (b) of this section].

"(2) Cap on Annual Amount of Recoupment.—With respect to overpayments to a hospital described in paragraph (1), the Secretary may not recoup more than 25 percent of the amount of such overpayments from the hospital during a fiscal year.

"(3) Effective Date.—Paragraphs (1) and (2) shall take effect October 1, 1990.

"(b) University Hospital Nursing Education.

"(1) In General.—The reasonable costs incurred by a hospital (or by an educational institution related to the hospital by common ownership or control) during a cost reporting period for clinical training (as defined by the Secretary) conducted on the premises of the hospital under approved nursing and allied health education programs that are not operated by the hospital shall be allowable as reasonable costs under part B of title XVIII of the Social Security Act and reimbursed under such part on a pass-through basis.

"(2) Conditions for Reimbursement.—The reasonable costs incurred by a hospital during a cost reporting period that ended on or before October 1, 1983, and before October 1, 1990, relating to approved nursing and allied health education programs did not meet the requirements for allowable nursing and allied health education costs (as developed by the Secretary pursuant to section 1861(v) of such Act [section 1395ww(v) of this title]) are not attributable to the clinical training costs during the cost reporting period described in subparagraph (A); and

"(B) the proportion of the hospital's total allowable costs that is attributable to the clinical training costs during the cost reporting period described in subparagraph (A); and

"(C) the hospital receives a benefit for the support it furnishes to such program through the provisions of clinical services by nursing or allied health students participating in such program; and

"(D) the costs incurred by the hospital for such program do not exceed the portion of total allowable costs that were attributable to clinical training costs during the cost reporting period described in subparagraph (A); and

"(3) Prohibition Against Recoupment of Costs by Secretary.—

"(A) In General.—The Secretary of Health and Human Services may not recoup payments from (or otherwise reduce or adjust payments under part B of title XVIII of the Social Security Act) to a hospital because of alleged overpayments described in sub-paragraph (A), the Secretary shall refund the amount recouped, reduced, or adjusted from the hospital.
beginning on or after October 1, 1983, and before October 1, 1990, relating to approved nursing and allied health education programs did not meet the requirements for allowable nursing and allied health education costs (as developed by the Secretary pursuant to section 1861(v) of such Act [section 1395x(v) of this title]).

(3) ROUNDS OF AMOUNTS RECOUPED.—If, prior to the date of the enactment of this Act [Nov. 5, 1990], the Secretary has recouped payments from (or otherwise reduced or adjusted payments under part B of title XVIII of the Social Security Act) a hospital because of overpayments described in subparagraph (A), the Secretary shall refund the amount recouped, reduced, or adjusted from the hospital.

(4) SPECIAL AUDIT TO DETERMINE COSTS.—In determining the amount of costs incurred by, claimed by, and reimbursed to, a hospital for purposes of this subsection, the Secretary shall conduct a special audit (or use such other appropriate mechanism) to ensure the accuracy of such past claims and payments.

(5) EFFECTIVE DATE.—Except as provided in paragraph (3), the provisions of this subsection shall apply to cost reporting periods beginning on or after October 1, 1990.

DEVELOPMENT OF NATIONAL PROSPECTIVE PAYMENT RATES FOR CURRENT NON-PPS HOSPITALS

Section 4005(b) of Pub. L. 101–508 provided that:

"(1) DEVELOPMENT OF PROPOSAL.—The Secretary of Health and Human Services shall develop a proposal to modify the current system under which hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act [as added by Pub. L. 102–430, subsec. (d)(1)(B) of this section]) receive payment for the operating and capital-related costs of inpatient hospital services under part A (part A of this subchapter) of the Medicare program or a proposal to replace such system with a system under which such payments would be made on the basis of nationally-determined average standardized amounts. In developing any proposal under this paragraph to replace the current system with a prospective payment system, the Secretary shall—

"(A) take into consideration the need to provide for appropriate limits on increases in expenditures under the Medicare program;

"(B) provide for adjustments to prospectively determined rates to account for changes in a hospital's case mix, severity of illness of patients, volume of cases, and the development of new technologies and standards of medical practice;

"(C) take into consideration the need to increase the payment otherwise made under such system in the case of services provided to patients whose length of stay or costs of treatment greatly exceed the length of stay or cost of treatment provided for under the applicable prospectively determined payment rate;

"(D) take into consideration the need to adjust payments under the system to take into account factors such as a disproportionate share of low-income patients, costs related to graduate medical education programs, differences in wages and wage-related costs among hospitals located in various geographic areas, and other factors the Secretary considers appropriate; and

"(E) provide for the appropriate allocation of operating and capital-related costs of hospitals not subject to the new prospective payment system and distinct units of such hospitals that would be paid under such system.

"(2) REPORTS.—(A) By not later than April 1, 1992, the Secretary shall submit the proposal developed under paragraph (1) to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives.

"(B) By not later than June 1, 1992, the Prospective Payment Assessment Commission shall submit an analysis of and comments on the proposal developed under paragraph (1) to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives."

GUIDANCE TO INTERMEDIARIES AND HOSPITALS

Section 4005(c)(3) of Pub. L. 101–508 provided that:

"The Administrator of the Health Care Financing Administration shall provide guidance to agencies and organizations performing functions pursuant to section 1816 of the Social Security Act [section 1395h of this title] and to hospitals that are not subsection (d) hospitals (as defined in section 1886(d)(1)(B) of such Act [subsec. (d)(1)(B) of this section]) to assist such agencies, organizations, and hospitals in filing complete applications with the Administrator for exemptions, exceptions, and adjustments under section 1886(b)(4)(A) of such Act."

FREEZE IN PAYMENTS UNDER PART A OF THIS SUBCHAPTER THROUGH DECEMBER 31, 1990

Section 4007 of Pub. L. 101–508 provided that:

"(a) IN GENERAL.—Notwithstanding any other provision of law, for purposes of determining the amount of payment for items or services under part A of title XVIII of the Social Security Act [part A of this subchapter] (including payments under section 1886 of such Act [this section] attributable to or allocated under such part) during the period described in subsection (b):

"(1) the market basket percentage increase (described in section 1886(b)(3)(B)(iii) of the Social Security Act) shall be deemed to be 0 for discharges occurring during such period.

"(2) The percentage increase or decrease in the medical care expenditure category of the consumer price index applicable under section 1814(i)(2)(B) of such Act (section 1895(i)(2)(B) of this title) shall be deemed to be 0.

"(3) The area wage index applicable to a subsection (d) hospital under section 1886(d)(3)(E) of such Act shall be deemed to be the area wage index applicable to such hospital as of September 30, 1990.

"(4) The percentage change in the consumer price index applicable under section 1886(h)(2)(D) of such Act shall be deemed to be 0.

"(b) DESCRIPTION OF PERIOD.—The period referred to in subsection (a) is the period beginning on October 21, 1990, and ending on December 31, 1990.

REVIEW OF HOSPITAL REGULATIONS WITH RESPECT TO RURAL HOSPITALS

Section 4008(l) of Pub. L. 101–508 provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services shall review the requirements applicable under title XVIII of the Social Security Act [this subchapter] to determine which requirements could be made less administratively and economically burdensome (without diminishing the quality of care) for hospitals defined in section 1886(d)(1)(B) of such Act [subsec. (d)(1)(B) of this section] that are located in a rural area (as defined in section 1886(d)(2)(D) of such Act). Such review shall specifically include standards related to staffing requirements.

"(2) REPORT.—The Secretary of Health and Human Services shall report to Congress by April 1, 1992, on the results of the review conducted under subsection (a), and include conclusions on which regulations, if any, should be modified with respect to hospitals described in subsection (a).

PROHIBITION ON COST SAVINGS POLICIES BEFORE BEGINNING OF FISCAL YEAR

Section 4207(b)(1), formerly 4207(b)(1), of Pub. L. 101–508, as renumbered and amended by Pub. L. 103–432, title I, §160(d)(4), (5)(C), Oct. 31, 1994, 108 Stat. 4444, provided that: ‘‘Notwithstanding any other provision of law, the Secretary of Health and Human Services may not issue any proposed or final regulation, instruction, or other policy which is estimated by the Secretary to result in a net reduction in expenditures under title
be classified as a sole community hospital after such date as a result of the amendments made by paragraph (1) [amending this section] shall continue to be classified as a sole community hospital for purposes of section 1886(d)(5)(D) of such Act [subsec. (d)(5)(D) of this section]."

Additional Payment Resulting From Corrections of Errorously Determined Wage Index

Section 6003(b)(5) of Pub. L. 101–239 provided that:

"(A) In general.—If the Secretary of Health and Human Services (hereinafter referred to as the 'Secretary') discovers an error with respect to the determination, adjustment, or computation of the area wage index described in section 1886(d)(3)(E) of the Social Security Act [subsec. (d)(3)(E) of this section] and subsequently corrects such error, the Secretary shall make an additional payment under title XVIII of such Act [this subchapter] to a hospital affected by such error for inpatient hospital discharges occurring during the period when the erroneously determined, adjusted, or computed wage index was in effect.

"(B) Conditions for additional payment.—A hospital is eligible for an additional payment under subparagraph (A) only if—

samath the error resulted from the submission of erroneous data, that a hospital is not eligible for such additional payment if it submitted such erroneous data;

(ii) the error was made with respect to the survey of the 1984 wages and wage-related costs of hospitals in the United States conducted under section 1886(d)(3)(E) of the Social Security Act; and

(iii) the correction of the error resulted in an adjustment to the area wage index of not less than 3 percent.

(C) Period of applicability.—A hospital may not receive an additional payment under subparagraph (A) for discharges occurring after October 1, 1990.''

Legislative Proposal Eliminating Separate Average Standardized Amounts


Determination and Recommendations of Payments for Costs of Administering Blood Clotting Factors to Individuals with Hemophilia

Section 601(b), (c) of Pub. L. 101–239 provided that:

"(b) Determining Payment Amount.—The Secretary of Health and Human Services shall determine the amount of payment made to hospitals under part A of title XVIII of the Social Security Act [part A of this subchapter] for the costs of administering blood clotting factors to individuals with hemophilia by multiplying a predetermined price per unit of blood clotting factor (determined in consultation with the Prospective Payment Assessment Commission) by the number of units provided to the individual.

"(c) Recommendations on Payments.—The Prospective Payment Assessment Commission and the Health Care Financing Administration shall develop recommendations with respect to payments to hospitals under part A of title XVIII of the Social Security Act for the costs of administering blood clotting factors to individuals with hemophilia, and shall submit such recommendations to Congress not later than 18 months after the date of enactment of this Act [Dec. 19, 1989]."
this Act [Dec. 19, 1989], the Secretary of Health and Human Services shall publish instructions specifying the application process to be used in providing exceptions and adjustments under section 1886(b)(3)(A) of the Social Security Act [subsec. (b)(3)(A) of this section]."

DELAY IN RECOVERY OF CERTAIN NURSING AND ALLIED EDUCATION COSTS

Section 6263(b) of Pub. L. 101–239 provided that:

"(1) The Secretary of Health and Human Services (in this subsection referred to as the 'Secretary') shall not, before October 1, 1990, recoup from, or otherwise reduce or adjust payments under title XVIII of the Social Security Act [this subchapter] to, hospitals because of alleged overpayments to such hospitals under such title due to a determination that costs which were reported by a hospital on its medicare cost reports relating to medicare beneficiaries resulting from the elimination of a day limitation on medicare inpatient hospital services (under the amendments made by section 101 [amending section 1395d of this title])"

ELECTION OF PERSONNEL POLICY FOR ProPAC EMPLOYEES

Section 6105 of Pub. L. 100–674 provided that: "With respect to employees of the Prospective Payment Assessment Commission hired before December 22, 1987, such employees shall have the option to elect within 60 days of the date of enactment of this Act [Nov. 10, 1988] to be covered under either the personnel policy in effect with respect to such employees before December 22, 1987, or under the provisions of the Federal Supplementary Medical Insurance Trust Fund established under subsection (a) for costs that may not make payment under the demonstration project in a public hospital that is located in a large urban area and that has established a triage system, under which the Secretary shall make payments out of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate in a year) for 3 years to reimburse the hospital for the reasonable costs of operating the system, including costs—

"(1) to train hospital personnel to operate and participate in the system; and

"(2) to provide services to patients who might otherwise be denied appropriate and prompt care.

"(b) LIMITATIONS ON PAYMENT.—(1) The Secretary may not make payment under the demonstration project established under subsection (a) for costs that the Secretary determines are not reasonable.

"(2) The amount of payment made under the demonstration project during a single year may not exceed $500,000."

TRANSMUTATION OF MOUNTS TO INPATIENT HOSPITAL SERVICES

Section 101(c)(2)(B) of title I of Pub. L. 101–234 provided that: "The Secretary of Health and Human Services shall make an appropriate adjustment to the target amount established under section 1886(b)(3)(A) of the Social Security Act [subsec. (b)(3)(A) of this section] and adjustments to hospital services provided to an inpatient whose stay began before January 1, 1990, in order to take into account the target amount that would have applied but for the amendments made by this title [see Tables for classification]."

ADJUSTMENTS IN PAYMENTS FOR INPATIENT HOSPITAL SERVICES


"(1) The Secretary shall establish a demonstration project in a public hospital that is located in a large urban area and that has established a triage system, under which the Secretary shall make payments out of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund (in such proportions as the Secretary determines to be appropriate in a year) for 3 years to reimburse the hospital for the reasonable costs of operating the system, including costs—

"(1) to train hospital personnel to operate and participate in the system; and

"(2) to provide services to patients who might otherwise be denied appropriate and prompt care.

"(b) LIMITATIONS ON PAYMENT.—(1) The Secretary may not make payment under the demonstration project established under subsection (a) for costs that the Secretary determines are not reasonable.

"(2) The amount of payment made under the demonstration project during a single year may not exceed $500,000."

PROPAC STUDY

Section 203(c)(2) of Pub. L. 100–360 directed Prospective Payment Assessment Commission to conduct a study, and make recommendations to Congress and Secretary of Health and Human Services by not later than Mar. 1, 1991, concerning appropriate adjustment to hospital payments provided under subsection (a) of this section for inpatient hospital services to account for reduced costs to hospitals resulting from amendments made by section 203 of Pub. L. 100–360, amendments sections 1320c–3, 1395d, 1395k to 1395n, 1395w–2, 1395x, 1395z, and 1395aa of this title, prior to repeal by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981.

CLINIC HOSPITAL WAGE INDICES

Section 4004(b) of Pub. L. 100–360 provided that: "In calculating the wage index under section 1886(d) of the
Social Security Act [subsec. (d) of this section] for purposes of making payment adjustments after September 30, 1988, as required under paragraphs (2)(H) and (3)(E) of such section, in the case of any institution which received the waiver specified in section 602(k) of the Social Security Amendments of 1983 [section 602(k) of Pub. L. 98-21, set out as a note under section 1398y of this title], the Secretary of Health and Human Services shall include wage costs paid to related organization employees directly involved in the delivery and administration of care provided by the related organization to hospital inpatients. For purposes of the preceding sentence, the term 'wage costs' does not include costs of overhead or home office administrative salaries or any costs that are not incurred in the hospital’s Metropolitan Statistical Area.

LIMITATION ON AMOUNTS PAID IN FISCAL YEARS 1988 AND 1989

Section 4005(c)(2)(B) of Pub. L. 100–203 provided that—

"(B) A hospital receiving a grant under this subsection shall take appropriate steps to ensure that the total amount paid in a fiscal year under title XVIII of the Social Security Act for the hospital, and for related organizations, is equal to the amount that would have been paid had the hospital been classified as a rural referral center as being located in a rural area for purposes of section 18201(d)(2) of the Social Security Act [section 1395d–41(2) of this title], or any non-Federal, short-term general acute care hospital that—

"(A) is located in a rural area (as determined in accordance with subsection (d)),

"(B) has less than 100 beds, and

"(C) is not for profit.

"(3)(A) Any eligible small rural hospital that desires to modify the type or extent of health care services that it provides in order to adjust for one or more of the factors specified in paragraph (1) may submit an application to the Administrator and a copy of such application to the Governor of the State in which it is located. The application shall specify the nature of the project proposed by the hospital, the data and information on which the project is based, and a timetable (of not more than 24 months) for completion of the project. The application shall be submitted on or before a date specified by the Administrator and shall be in such form as the Administrator may require.

"(B) The Governor shall transmit to the Administrator, within a reasonable time after receiving a copy of an application pursuant to subparagraph (A), any comments with respect to the application that the Governor deems appropriate.

"(C) The Governor of a State may designate an appropriate State agency to receive and comment on applications submitted under subparagraph (A).

"(4) A hospital shall be considered to be located in a rural area for purposes of this subsection if it is treated as being located in a rural area for purposes of section 1886(d)(3)(D) of the Social Security Act [subsec. (d)(3)(D) of this section].

"(5) In determining which hospitals making application under paragraph (3) will receive grants under this subsection, the Administrator shall take into account—

"(A) any comments received under paragraph (3)(B) with respect to a proposed project;

"(B) the effect that the project will have on—

"(i) reducing expenditures from the Federal Hospital Insurance Trust Fund,

"(ii) improving the access of Medicare beneficiaries to health care of a reasonable quality; and

"(C) the degree of coordination that may be expected between the proposed project and—

"(i) other local or regional health care providers, and

"(ii) community and government leaders, as evidenced by the availability of support for the project (in cash or in kind) and other relevant factors.

"(6) A grant to a hospital under this subsection may not exceed $50,000 a year and may not exceed a term of 3 years.

"(7)(A) Except as provided in subparagraphs (B) and (C), a hospital receiving a grant under this subsection may use the grant for any of expenses incurred in planning and implementing the project with respect to which the grant is made.

"(B) A hospital receiving a grant under this subsection for a project may not use the grant to retire
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PAYMENT FOR RURAL HEALTH CARE

a hospital receiving a grant under this section (amending this section and section 1395t of this title and enacting provisions set out as notes under this section and section 1395t of this title) shall furnish the Administrator with such information as the Administrator may require to evaluate the project with respect to which the grant is made and to ensure that the grant is expended for the purposes for which it was made.

(B) The Administrator shall report to the Congress at least once every 12 months on the program of grants established under this subsection. The report shall assess the functioning and status of the program, shall evaluate the progress made toward achieving the purposes of the program, and shall include any recommendations the Secretary may deem appropriate with respect to the program.

(C) The Administrator shall submit a final report on the program to the Congress not later than 180 days after all projects receiving a grant under the program are completed.

(9) For purposes of carrying out the program of grants under this subsection, there are authorized to be appropriated from the Federal Hospital Insurance Trust Fund $15,000,000 for fiscal year 1989, $25,000,000 for each of fiscal years 1993 through 1997.

For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103-7 (in which item 6 on page 105 identifies a reporting provision which, as subsequently amended, is contained in section 4005(e)(8)(B) of Pub. L. 100-203, set out above), see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.

[Section 103(a)(2) of Pub. L. 103-432 provided that: ``(a) Development of Data Base.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall develop and place into effect a uniform system for the reporting by medicare participating hospitals of balance sheet and information described in paragraph (2) in conducting the project, the Secretary shall require hospitals in at least 2 States, one of which maintains a uniform hospital reporting system, to report such information based on standard information established by the Secretary.

(2) The information described in this paragraph is as follows:

(A) Hospital discharges (classified by class of primary payer).

(B) Patient days (classified by class of primary payer).

(C) Licensed beds, staffed beds, and occupancy.

(D) Inpatient charges and revenues (classified by class of primary payer).

(E) Outpatient charges and revenues (classified by class of primary payer).

(F) Inpatient and outpatient hospital expenses (by cost-center classified for operating and capital).

(G) Reasonable costs.

(H) Other income.

(I) Bad debt and charity care.

(J) Capital acquisitions.

(K) Capital assets.

The Secretary shall develop a definition of 'outpatient visit' for purposes of reporting hospital information.

(3) The Secretary shall develop the system under subsection (c) in a manner so as:

(A) to facilitate the submittal of the information in the report in an electronic form, and

(B) to be compatible with the needs of the medicare prospective payment system.

(4) The Secretary shall prepare and submit, to the Prospective Payment Assessment Commission, the Comptroller General, the Committee on Ways and Means of the House of Representatives, and the Committee on Finance of the Senate, by not later than 45 days after the end of each calendar quarter, data collected under the system.

(5) In paragraph (2):

(A) The term 'bad debt and charity care' has such meaning as the Secretary establishes.

(B) The term 'class' means, with respect to payers at least, the program under this title XVIII of the Social Security Act [this subchapter], a State plan approved under title XIX of such Act [subchapter XIX of this chapter], other third party-payers, and other persons (including self-paying individuals).

(6) The Secretary shall set aside at least a total of $3,000,000 for fiscal years 1989, 1990, and 1991 from expenditures under the system.

(7) The Comptroller General shall analyze the adequacy of the existing system for reporting of hospital information and the costs and benefits of data report-
HOSPITAL OUTLIER PAYMENTS AND POLICY

Section 4008(d) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 411(b)(7), July 1, 1988, 102 Stat. 771, provided that:

“(1) INCREASE IN OUTLIER PAYMENTS FOR BURN CENTER DRG.—

“(A) IN GENERAL.—For discharges classified in diagnosis-related groups relating to burn cases and occurring on or after April 1, 1988, and before October 1, 1989, the marginal cost of care permitted by the Secretary of Health and Human Services under section 1886(d)(5)(A)(i) of the Social Security Act [subsection (d)(5)(A) of this section] shall be 90 percent of the appropriate per diem cost of care or 90 percent of the cost for cost outliers.

“(B) BUDGET NEUTRALITY.—Subparagraph (A) shall be implemented in a manner that ensures that total payments under section 1886(d) of the Social Security Act are not increased or decreased by reason of the adjustments required by such subparagraph.

“(2) LIMITATION ON CHANGES IN OUTLIER REGULATIONS.—

“(A) IN GENERAL.—Notwithstanding any other provision of law, except as required to implement specific provisions required under statute, the Secretary of Health and Human Services is not authorized to issue in final form, after the date of the enactment of this Act [Dec. 22, 1987] and before September 1, 1988, any final regulation which changes the method of payment for outlier cases under section 1886(d)(5)(A) of the Social Security Act [subsection (d)(5)(A) of this section].

“(B) PROPAC REPORT.—The chairman of the Prospective Payment Assessment Commission shall report to the Congress and the Secretary of Health and Human Services, by not later than June 1, 1988, on the method of payment for outlier cases under such section and providing more adequate and appropriate payments with respect to burn center cases.

“(3) REPORT ON OUTLIER PAYMENTS.—The Secretary of Health and Human Services shall include in the annual report submitted to the Congress pursuant to section 1875(b) of the Social Security Act [section 1395(b) of this title] a comparison with respect to hospitals located in an urban area and hospitals located in a rural area, of the amount of reductions under section 1886(d)(5)(B) of the Social Security Act [subsection (d)(5)(B) of this section] and additional payments under section 1886(d)(5)(A) of such Act.

PROPAC STUDIES AND REPORTS

Section 4008(h) of Pub. L. 100–203 provided that:

“(1) PROPAC REPORTS ON STUDY OF DRG RATES FOR HOSPITALS IN RURAL AND URBAN AREAS.—The Prospective Payment Assessment Commission shall evaluate the study conducted by the Secretary of Health and Human Services pursuant to section 609(a)(2)(C)(i) of the Social Security Amendments of 1986 [section 609(a)(2)(C)(i) of Pub. L. 99–21, set out below] (relating to the feasibility, impact, and desirability of eliminating or phasing out separate urban and rural DRG prospective payment rates and report its conclusions and recommendations to the Congress not later than March 1, 1988.

“(2) PROPAC REPORT ON SEPARATE URBAN PAYMENT RATES.—The Prospective Payment Assessment Commission shall evaluate the desirability of maintaining separate DRG prospective payment rates for hospitals located in large urban areas (as defined in section 1886(d)(2)(D)) of the Social Security Act [subsection (d)(2)(D) of this section] and shall report to Congress on such evaluation not later than January 1, 1989.

“(3) REPORT ON ADJUSTMENT FOR NON-LABOR COSTS.—The Prospective Payment Assessment Commission shall perform an analysis to determine the feasibility and appropriateness of adjusting the non-wage-related portion of the adjusted average standardized amounts under section 1886(d)(3) of the Social Security Act [subsection (d)(3) of this section] based on area differences in hospitals’ costs (other than wage-related costs) and input prices. The Commission shall report to the Congress on such analysis by not later than October 1, 1989.

SPECIAL RULE FOR URBAN AREAS IN NEW ENGLAND

Section 4009(k) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 411(b)(8)(C), July 1, 1988, 102 Stat. 772, provided that: ‘‘In the case of urban areas in New England, the Secretary of Health and Human Services shall apply the second sentence of section 1886(d)(2)(D) of the Social Security Act [subsection (d)(2)(D) of this section] as amended by section 652(b) of this subtitle, as though 970,000 were substituted for 1,000,000.’’

RURAL HEALTH MEDICAL EDUCATION DEMONSTRATION PROJECT


“(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall enter into agreements with 10 sponsoring hospitals submitting applications under this subsection to conduct demonstration projects to assist resident physicians in developing field clinical experience in rural areas.

“(b) NATURE OF PROJECT.—Under a demonstration project conducted under subsection (a), a sponsoring hospital entering into an agreement with the Secretary under such subsection shall enter into arrangements with a small rural hospital to provide to such rural hospital, for a period of one to three months of training, physicians (in such number as the agreement under subsection (a) may provide) who have completed one year of residency training.

“(c) SELECTION.—(1) In selecting from among applications submitted under subsection (a), the Secretary shall ensure that four small rural hospitals located in different counties participate in the demonstration project and that—

“(A) two of such hospitals are located in rural counties of more than 7,700 square miles (one of which is east of the Mississippi River and one of which is west of such river); and

“(B) two of such hospitals are located in rural areas with (as determined by the Secretary) a severe shortage of physicians (one of which is east of the Mississippi River and one of which is west of such river).

“(2) The provisions of paragraph (1) shall not apply with respect to applications submitted as a result of amendments made by section 6216 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239, amending this note].

“(d) CLARIFICATION OF PAYMENT.—For purposes of section 1886 of the Social Security Act [this section]—

“(1) with respect to subsection (d)(5)(B) of such section, any resident physician participating in the project under subsection (a) for any part of a year shall be treated as if he or she were working at the appropriate sponsoring hospital with an agreement under subsection (a) on September 1 of such year (and shall not be treated as if working at the small rural hospital); and

“(2) with respect to subsection (h) of such section, the payment amount permitted under such subsection for a sponsoring hospital with an agreement under subsection (a) shall be increased (for the duration of such project) by an amount equal to the amount of any direct graduate medical education costs (as defined in paragraph (5) of such subsection.)
in fiscal year 1991 of more than $50,000,000."

DEFINITION.—Each demonstration project under subsection (a) shall be commenced not later than six months after the date of enactment of this Act (Dec. 22, 1987) or the date of the enactment of the Omnibus Budget Reconciliation Act of 1989 (Dec. 19, 1989), in the case of a project conducted as a result of the amendments made by section 6216 of such Act [Pub. L. 101–239, amending this note] and shall be conducted for a period of three years.

(1) DEFINITION.—In this section, the term 'sponsoring hospital' means a hospital that receives payments under sections 1886(d)(5)(B) and 1886(h) of the Social Security Act [subsecs. (d)(5)(B) and (h) of this section].

PROHIBITION ON POLICY BY SECRETARY OF HEALTH AND HUMAN SERVICES TO REDUCE EXPENDITURES IN FISCAL YEARS 1989, 1990, AND 1991

Section 4039(d) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 426(e), July 1, 1988, 102 Stat. 814; Pub. L. 101–239, title VI, § 6207(b), Dec. 19, 1989, 103 Stat. 2245, provided that: "Notwithstanding any other provision of law, except as required to implement specific provisions required under statute, the Secretary of Health and Human Services is not authorized to issue in final form, after the date of the enactment of this Act (Dec. 22, 1987) and before October 15, 1990, any regulation, instruction, or other policy which is estimated by the Secretary to result in a net reduction in expenditures under title XVIII of the Social Security Act [this subchapter] in fiscal year 1989 or in fiscal year 1990 or in fiscal year 1991 of more than $50,000,000."

TEMPORARY EXTENSION OF PAYMENT POLICIES FOR INPATIENT HOSPITAL SERVICES


"(A) TEMPORARY FREEZE IN PPS HOSPITAL RATES.—For purposes of subsection (a) of such section for discharges occurring during the period beginning on October 1, 1987, and ending on November 20, 1987 (in this paragraph referred to as the 'extension period'), the applicable percentage increase under subsection (b)(3)(B) of such section with respect to fiscal year 1988 is deemed to be 0 percent.

"(B) TEMPORARY FREEZE IN PAYMENT BASE.—(i) extension of blended DRG rate.—For purposes of subsection (d)(1) of such section, the 'applicable combined adjusted DRG prospective payment rate' for discharges occurring—(A) during the extension period is the rate specified in subsection (d)(1)(D)(ii) of such section, or

"(ii) after such period is the national adjusted prospective payment rate determined under subsection (d)(3) of such section.

"(ii) Extension of hospital-specific payment.—For the first 51 days of a hospital cost reporting period beginning during fiscal year 1988, payment shall be made under clause (ii) (rather than clause (i)) of subsection (d)(1)(A) of such section (subject to clause (i) of this subparagraph), the target percentage and DRG percentage shall be those specified in subsection (d)(1)(C)(ii) of such section, and the applicable percentage increase in a hospital's target amount shall be deemed to be 0 percent.

"(C) TEMPORARY FREEZE IN AMOUNTS OF PAYMENT FOR OUTLIE..—For purposes of payment under paragraph (b) of such section for discharges occurring in fiscal year 1988, subsection (g)(2) of such section shall be applied as though the applicable percentage were 3.5 percent.

"(D) TEMPORARY FREEZE IN RETURN ON EQUITY REDUCTIONS.—For the first 51 days of a cost reporting period beginning during fiscal year 1988, subsection (g)(2) of such section shall be applied as though the applicable percentage were 75 percent.

"(E) TEMPORARY FREEZE ON PAYMENTS RATES FOR PPS-EXEMPT HOSPITALS.—For purposes of payment under subsection (b) of such section for cost reporting periods beginning during fiscal year 1988, with respect to the first 51 days of such period the applicable percentage increase under paragraph (3)(B) of such subsection is deemed to be 0 percent."

Maintenance current outlier policy in fiscal year 1987

Section 9302(b) of Pub L. 99–509 provided that: "For payments made under section 1886(d) of the Social Security Act [subsec. (d) of this section] for discharges occurring in fiscal year 1987—

"(A) the proportions under paragraph (3)(B) for hospitals located in urban and rural areas shall be established at such levels as produce the same total dollar reduction under such paragraph as if this section had not been enacted; and

"(B) the thresholds and standards used for making additional payments under paragraph (5) of such section shall be the same as those in effect as of October 1, 1986."

EXTENSION OF REGIONAL REFERRAL CENTER CLASSIFICATION

Section 6003(d) of Pub. L. 100–239 provided that: "Any hospital that is classified as a regional referral center
under section 1886(d)(5)(C) of the Social Security Act [subsec. (d)(5)(C) of this section] as of September 30, 1989, including a hospital so classified as a result of section 902(d)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509, set out below], shall continue to be classified as a regional referral center for cost reporting periods beginning on or after October 1, 1989, before September 1, 1986, and before November 21, 1967, any regulation that changes the methodology for computing the amount of payment for capital-related costs (as defined under this paragraph (4)) for inpatient hospital services under part A of title XVIII of the Social Security Act [part A of this subchapter]. Any regulation published in violation of the previous sentence is void and of no effect.

"(2) NOT INCLUDING CAPITAL-RELATED COSTS IN BUDGET BASELINE.—Any reference in law to a regulation issued in final form or proposed by the Health Care Financing Administration pursuant to sections 1886(b)(3)(B), 1886(d)(3)(A), and 1886(e)(4) of the Social Security Act [subsecs. (b)(3)(B), (d)(3)(A), and (e)(4) of this section] shall not include any regulation issued or proposed with respect to capital-related costs (as defined in paragraph (4))."

"(3) EXCEPTION.—Paragraph (1) shall not apply to any regulation issued for the sole purpose of implementing section 1886(d)(1)(O) and 1886(g)(2) of the Social Security Act [section 1886(d)(1)(O) and 1886(g)(2) of this title and subsection (c) of this section] and section 1886(g)(2)(A) and (B) of the Social Security Act [subsec. (g)(2)(A) and (B) of this section] (as amended by section 222(a) of the Act).

"(4) CAPITAL-RELATED COSTS DEFINED.—In this subsection, the term 'capital-related costs' means those capital-related costs that are specifically excluded, under the second sentence of section 1886(a)(4) of the Social Security Act [subsec. (a)(4) of this section], from the term 'operating costs of inpatient hospital services' (as defined in that section) for cost reporting periods beginning prior to October 1, 1987.

LIMITATION ON AUTHORITY TO ISSUE CERTAIN FINAL REGULATIONS AND INSTRUCTIONS RELATING TO HOSPITALS OR PHYSICIANS

Section 9321(b) of Pub. L. 99–509 provided that: "Notwithstanding any other provision of law, except as required to implement specific provisions required under statute and except as provided under subsection (c) [set out above] with respect to a regulation described in that subsection, the Secretary of Health and Human Services is not authorized to issue in final form after the date of the enactment of this Act [Oct. 21, 1986] and before September 1, 1987, any regulation, instruction, or other policy which is estimated by the Secretary to result in a net reduction in expenditures under title XVIII of the Social Security Act [this subchapter] in fiscal year 1988 of more than $50,000,000, and which relates to hospitals or physicians.

STUDY OF METHODOLOGY FOR AREA WAGE ADJUSTMENT FOR CENTRAL CITIES; REPORT TO CONGRESS

Section 9103(b) of Pub. L. 99–272 provided that: "(1) The Secretary shall report to Congress on the information collected and the methodologies developed under paragraph (1) not later than May 1, 1987. The report shall include a recommendation as to the feasibility and desirability of implementing such methodologies.

CONTINUATION OF MEDICARE REIMBURSEMENT WAIVERS FOR CERTAIN HOSPITALS PARTICIPATING IN REGIONAL HOSPITAL REIMBURSEMENT DEMONSTRATIONS

Section 9108 of Pub. L. 99–272 provided that:

"(1) PROHIBITION OF ISSUANCE OF FINAL REGULATIONS ON CAPITAL-RELATED COSTS AS PART OF PAYMENT FOR OPERATING COSTS BEFORE NOVEMBER 21, 1967.—Notwithstanding any other provision of law (except as provided in paragraph (3)), the Secretary of Health and Human Services may not issue, in final form, after September 1, 1986, and before November 21, 1967, any regulation that changes the methodology for computing the amount of payment for capital-related costs (as defined under this paragraph (4) for inpatient hospital services under part A of title XVIII of the Social Security Act [part A of this subchapter]. Any regulation published in violation of the previous sentence is void and of no effect.

"(2) NOT INCLUDING CAPITAL-RELATED COSTS IN BUDGET BASELINE.—Any reference in law to a regulation issued in final form or proposed by the Health Care Financing Administration pursuant to sections 1886(b)(3)(B), 1886(d)(3)(A), and 1886(e)(4) of the Social Security Act [subsecs. (b)(3)(B), (d)(3)(A), and (e)(4) of this section] shall not include any regulation issued or proposed with respect to capital-related costs (as defined in paragraph (4))."

"(3) EXCEPTION.—Paragraph (1) shall not apply to any regulation issued for the sole purpose of implementing section 1886(d)(1)(O) and 1886(g)(2) of the Social Security Act [section 1886(d)(1)(O) and 1886(g)(2) of this title and subsection (c) of this section] and section 1886(g)(2)(A) and (B) of the Social Security Act [subsec. (g)(2)(A) and (B) of this section] (as amended by section 222(a) of the Act).

"(4) CAPITAL-RELATED COSTS DEFINED.—In this subsection, the term 'capital-related costs' means those capital-related costs that are specifically excluded, under the second sentence of section 1886(a)(4) of the Social Security Act [subsec. (a)(4) of this section], from the term 'operating costs of inpatient hospital services' (as defined in that section) for cost reporting periods beginning prior to October 1, 1987.

LIMITATION ON AUTHORITY TO ISSUE CERTAIN FINAL REGULATIONS AND INSTRUCTIONS RELATING TO HOSPITALS OR PHYSICIANS

Section 9321(b) of Pub. L. 99–509 provided that: "Notwithstanding any other provision of law, except as required to implement specific provisions required under statute and except as provided under subsection (c) [set out above] with respect to a regulation described in that subsection, the Secretary of Health and Human Services is not authorized to issue in final form after the date of the enactment of this Act [Oct. 21, 1986] and before September 1, 1987, any regulation, instruction, or other policy which is estimated by the Secretary to result in a net reduction in expenditures under title XVIII of the Social Security Act [this subchapter] in fiscal year 1988 of more than $50,000,000, and which relates to hospitals or physicians.

STUDY OF METHODOLOGY FOR AREA WAGE ADJUSTMENT FOR CENTRAL CITIES; REPORT TO CONGRESS

Section 9103(b) of Pub. L. 99–272 provided that: "(1) The Secretary shall report to Congress on the information collected and the methodologies developed under paragraph (1) not later than May 1, 1987. The report shall include a recommendation as to the feasibility and desirability of implementing such methodologies.

CONTINUATION OF MEDICARE REIMBURSEMENT WAIVERS FOR CERTAIN HOSPITALS PARTICIPATING IN REGIONAL HOSPITAL REIMBURSEMENT DEMONSTRATIONS

Section 9108 of Pub. L. 99–272 provided that:

"(1) PROHIBITION OF ISSUANCE OF FINAL REGULATIONS ON CAPITAL-RELATED COSTS AS PART OF PAYMENT FOR OPERATING COSTS BEFORE NOVEMBER 21, 1967.—Notwithstanding any other provision of law (except as provided in paragraph (3)), the Secretary of Health and Human Services may not issue, in final form, after September 1, 1986, and before November 21, 1967, any regulation that changes the methodology for computing the amount of payment for capital-related costs (as defined under this paragraph (4) for inpatient hospital services under part A of title XVIII of the Social Security Act [part A of this subchapter]. Any regulation published in violation of the previous sentence is void and of no effect.

"(2) NOT INCLUDING CAPITAL-RELATED COSTS IN BUDGET BASELINE.—Any reference in law to a regulation issued in final form or proposed by the Health Care Financing Administration pursuant to sections 1886(b)(3)(B), 1886(d)(3)(A), and 1886(e)(4) of the Social Security Act [subsecs. (b)(3)(B), (d)(3)(A), and (e)(4) of this section] shall not include any regulation issued or proposed with respect to capital-related costs (as defined in paragraph (4))."

"(3) EXCEPTION.—Paragraph (1) shall not apply to any regulation issued for the sole purpose of implementing section 1886(d)(1)(O) and 1886(g)(2) of the Social Security Act [section 1886(d)(1)(O) and 1886(g)(2) of this title and subsection (c) of this section] and section 1886(g)(2)(A) and (B) of the Social Security Act [subsec. (g)(2)(A) and (B) of this section] (as amended by section 222(a) of the Act).

"(4) CAPITAL-RELATED COSTS DEFINED.—In this subsection, the term 'capital-related costs' means those capital-related costs that are specifically excluded, under the second sentence of section 1886(a)(4) of the Social Security Act [subsec. (a)(4) of this section], from the term 'operating costs of inpatient hospital services' (as defined in that section) for cost reporting periods beginning prior to October 1, 1987.

LIMITATION ON AUTHORITY TO ISSUE CERTAIN FINAL REGULATIONS AND INSTRUCTIONS RELATING TO HOSPITALS OR PHYSICIANS

Section 9321(b) of Pub. L. 99–509 provided that: "Notwithstanding any other provision of law, except as required to implement specific provisions required under statute and except as provided under subsection (c) [set out above] with respect to a regulation described in that subsection, the Secretary of Health and Human Services is not authorized to issue in final form after the date of the enactment of this Act [Oct. 21, 1986] and before September 1, 1987, any regulation, instruction, or other policy which is estimated by the Secretary to result in a net reduction in expenditures under title XVIII of the Social Security Act [this subchapter] in fiscal year 1988 of more than $50,000,000, and which relates to hospitals or physicians.

STUDY OF METHODOLOGY FOR AREA WAGE ADJUSTMENT FOR CENTRAL CITIES; REPORT TO CONGRESS

Section 9103(b) of Pub. L. 99–272 provided that: "(1) The Secretary shall report to Congress on the information collected and the methodologies developed under paragraph (1) not later than May 1, 1987. The report shall include a recommendation as to the feasibility and desirability of implementing such methodologies.

CONTINUATION OF MEDICARE REIMBURSEMENT WAIVERS FOR CERTAIN HOSPITALS PARTICIPATING IN REGIONAL HOSPITAL REIMBURSEMENT DEMONSTRATIONS

Section 9108 of Pub. L. 99–272 provided that:
"(a) CONTINUATION OF WAIVERS.—A hospital reimbursement control system which, on January 1, 1985, was carrying out a demonstration under a contract which had been approved by the Secretary of Health and Human Services pursuant to section 222(a) of the Social Security Amendments of 1972 [section 222(a) of Pub. L. 92–603, set out as a note under section 1385–1 of this title], or under section 402 of the Social Security Amendments of 1967 (as amended by section 222(b) of the Social Security Amendments of 1972) [section 1385–1 of this title], shall be deemed to meet the requirements of section 1886(c)(1)(A) of the Social Security Act [subsec. (c)(1)(A) of this section] if such system applies—

"(1) to substantially all non-Federal acute care hospitals (as defined by the Secretary) in the geographic area served by such system on January 1, 1985, and

"(2) to the review of at least 75 percent of—

"(A) all revenues or expenses in such geographic area for inpatient hospital services, and

"(B) revenues or expenses in such geographic area for inpatient hospital services provided under the State's plan approved under title XIX [subchapter XIX of this chapter]."

"(b) APPROVAL.—In the case of a hospital cost control system described in subsection (a), the requirements of section 1886(c) of the Social Security Act [subsec. (c) of this section] which apply to States shall instead apply to such system and, for such purposes, any reference to a State is deemed a reference to such system.

"(c) EFFECTIVE DATE.—This section shall become effective on the date of the enactment of this Act [Apr. 7, 1986]."

INFORMATION ON IMPACT OF FPS PAYMENTS ON HOSPITALS

Section 9114 of Pub. L. 99–272 provided that:

"(a) DISCLOSURE OF INFORMATION.—The Secretary of Health and Human Services shall make available to the Prospective Payment Assessment Commission, the Congressional Budget Office, the Comptroller General, the Prospective Payment Assessment Commission, the Congressional Budget Office, the Comptroller General, the Health and Human Services shall make available to the

"(b) CONFIDENTIALITY.—Information disclosed under subsection (a) shall be treated as confidential and shall not be subject to further disclosure in a manner that permits the identification of individual hospitals.''

SPECIAL RULES FOR IMPLEMENTATION OF HOSPITAL REIMBURSEMENT

Section 9115 of Pub. L. 99–272 provided that:

"(a) WAIVER OF PAPERWORK REDUCTION.—Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this subpart and implementing the amendments made by this subpart (subpart A (§9101–9115) of part 1 of subtitle A of title IX of Pub. L. 99–272, see Tables for classification).

"(b) USE OF INTERIM REGULATIONS.—The Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) as may be necessary to implement this subpart and the amendments made by this subpart.''

APPOINTMENT OF ADDITIONAL MEMBERS TO PROSPECTIVE PAYMENT ASSESSMENT COMMISSION

Section 9127(b) of Pub. L. 99–272, as amended by Pub. L. 99–514, title XVIII, §1885(b)(b), Oct. 22, 1986, 100 Stat. 2933, provided that: "The Secretary of Education shall appoint for this section the additional members of the Prospective Payment Assessment Commission as required by the amendment made by subsection (a) [amending this section] no later than 60 days after the date of the enactment of this Act [Apr. 7, 1986], for terms of three years, except that the Director may provide initially for such terms as will insure that (on a continuing basis) the terms of no more than eight members will expire in any one year.''

STUDIES BY SECRETARY; GAO STUDY; REPORT ON UNIFORMITY OF APPROVED FTE RESIDENT AMOUNTS; STUDY ON FOREIGN MEDICAL GRADUATES; ESTABLISHING PHYSICIAN IDENTIFIER SYSTEM; PAPERWORK REDUCTION


"(c) STUDIES BY SECRETARY.—(1) The Secretary of Health and Human Services shall conduct a study with respect to approved educational activities relating to nursing and other health professions for which reimbursement is made to hospitals under title XVIII of the Social Security Act [this subchapter]. The study shall address—

"(A) the types and numbers of such programs, and

"(B) the fiscal and administrative relationships between the hospitals involved and the schools with which the programs and students are affiliated;

"(C) the types and amounts of expenses of such programs for which reimbursement is made, and the financial and other contributions which accrue to the hospital as a consequence of having such programs.

The Secretary shall report the results of such study to the Committee on Finance of the Senate and the Committees on Ways and Means and Energy and Commerce of the House of Representatives prior to December 31, 1987.

"(2) The Secretary shall conduct a separate study of the advisability of continuing or terminating the exception under section 1886(b)(5)(F)(ii) of the Social Security Act [subsec. (h)(5)(F)(ii) of this section] for geriatric residencies and fellowships, and of expanding such exception to cover other educational activities, particularly those which are necessary to meet the projected health care needs of Medicare beneficiaries. Such study shall also examine the adequacy of the supply of faculty in the field of geriatrics. The Secretary shall report the results of such study to the committees described in paragraph (1) prior to July 1, 1990.

"(d) GAO STUDY.—(1) The Comptroller General shall conduct a study of the variation in the amounts of payments made under title XVIII of the Social Security Act [this subchapter] with respect to patients in different teaching hospital settings and in the amounts of such payments which are made with respect to patients who are treated in teaching and nonteaching hospital settings. Such study shall identify the components of such payments (including payments with respect to inpatient hospital services, physicians’ services, and capital costs, and, in the case of teaching hospital patients, payments with respect to direct and indirect teaching costs) and shall account, to the extent feasible, for any variations in the amounts of the payment components between teaching and nonteaching settings and among different teaching settings.

In carrying out such study, the Comptroller General may utilize a sample of hospital patients and any other data sources which he deems appropriate, and shall, to the extent feasible, control for differences in severity of illness levels, area wage levels, levels of physician reasonable charges for like services and procedures, and for other factors which could affect the comparability of patients and of payments between teaching and nonteaching settings and among teaching settings. The information obtained in the study shall be coordinated with the information obtained in conducting the study of teaching physicians’ services under section 1395u of this title.
“(3) The Comptroller General shall report the results of the study to the committees described in subsection (c)(1) prior to December 31, 1987.

“(c) REPORT ON UNIFORMITY OF APPROVED FTE RESIDENT AMOUNTS.—The Secretary of Health and Human Services shall report to the committees described in subsection (c)(1), not later than December 31, 1987, on whether section 1886(b)(3) of the Social Security Act [subsec. (h) of this section] should be revised to provide for greater uniformity in the approved FTE resident amounts established under paragraph (2) of that section and, if so, how such revisions should be implemented.

“(f) STUDY ON FOREIGN MEDICAL GRADUATES.—The Secretary of Health and Human Services shall study, and report to the committees described in subsection (c)(1), not later than December 31, 1987, respecting the use of physicians who are foreign medical graduates (within the meaning of section 1886(b)(5)(D) of the Social Security Act [subsec. (h)(5)(D) of this section]) in the provision of health care services (particularly inpatient and outpatient hospital services) to Medicare beneficiaries. Such study shall evaluate—

“(1) the types of services provided;

“(2) the cost of providing such services, relative to the cost of other physicians providing the services or other approaches to providing the services;

“(3) any deficiencies in the quality of the services provided, and methods of assuring the quality of such services; and

“(4) the impact on costs of and access to services if Medicare payment for hospitals’ costs of graduate medical education of foreign medical graduates were phased out.

“(g) PAPERWORK REDUCTION.—Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this section and the amendments made by this section [amending section 1395s of this title and enacting notes set out under this section and section 1395x of this title].

SPECIAL TREATMENT OF STATES FORMERLY UNDER WAIVER

Section 2920(f) of Pub. L. 99–272, as amended by Pub. L. 99–514, title X VIII, §1885(b)(10), Oct. 22, 1986, 100 Stat. 2933, provided that: “In the case of a hospital in a State that has had a waiver approved under section 1886(c) of the Social Security Act [subsec. (c) of this section] or section 462 of the Social Security Amendments of 1967 [section 1395b–1 of this title], for cost reporting periods beginning on or after January 1, 1986, if the waiver is terminated—

“(1) the Secretary of Health and Human Services shall permit the hospital to change the method by which it allocates administrative and general costs to the direct medical education cost centers to the method specified in the Medicare cost report;

“(2) the Secretary may make appropriate adjustments in the regional adjusted DRG prospective payment rate (for the region in which the State is located), based on the assumption that all teaching hospitals in the State use the Medicare cost report; and

“(3) the Secretary shall adjust the hospital-specific portion of payment under section 1886(d) of such Act [subsec. (d) of this section] for any such hospital that actually chooses to use the Medicare cost report. The Secretary shall implement this subsection based on the best available data.”

MORATORIUM ON LABORATORY PAYMENT PROVISIONS; REPORT TO CONGRESS


“(a) MORATORIUM.—Prior to January 1, 1990, the Secretary of Health and Human Services shall not conduct any demonstration projects relating to competitive bidding as a method of purchasing laboratory services under title XVIII of the Social Security Act [this subchapter]. The Secretary may contract for the design of, and site selection for, such demonstration projects.

“(b) COOPERATION IN STUDY ON TERMINATION OF THE COMPTROLLER.—The Secretary of Health and Human Services and the Comptroller General shall assist representatives of clinical laboratories in the industry’s conduct of a study to determine whether methods exist which are better than competitive bidding for purposes of utilizing competitive market forces in setting payment levels for laboratory services under title XVIII of the Social Security Act [this subchapter]. If such a study is conducted by the clinical laboratory industry, the Secretary and the Comptroller General shall comment on such study and submit such comments and the study to the Senate Committee on Finance and the House Committees on Ways and Means and Energy and Commerce.”

MEDICARE HOSPITAL AND PHYSICIAN PAYMENT PROVISIONS; EXTENSION PERIOD


“(a) MAINTAINING EXISTING HOSPITAL PAYMENT RATES.—Notwithstanding any other provision of law, the amount of payment under section 1886 of the Social Security Act [this section] for inpatient hospital services for discharges occurring (and cost reporting periods beginning during the extension period as defined in subsection (c)) shall be determined on the same basis as the amount of payment for such services for a discharge occurring on (or the cost reporting period beginning immediately on or before) September 30, 1985.

“(b) MAINTAINING EXISTING PAYMENT RATES FOR PHYSICIANS’ SERVICES.—Notwithstanding any other provision of law, the amount of payment under part B of title XVIII of the Social Security Act [part B of this subchapter] for physicians’ services which are furnished during the extension period (as defined in subsection (c)) shall be determined on the same basis as the amount of payment for such services furnished on September 30, 1985, and the 15-month period, referred to in section 1422(v)(1) of such Act [section 1395ww(g)(1)(A) of this title], shall be deemed to include the extension period.

“(c) EXTENSION PERIOD DEFINED.—

“(1) HOSPITAL PAYMENTS.—For purposes of subsection (a), the term ‘extension period’ means the period beginning on October 1, 1985, and ending on April 30, 1986.

“(2) PHYSICIAN PAYMENTS.—For purposes of subsection (b), the term ‘extension period’ means the period beginning on October 1, 1985, and ending on April 30, 1986.


DEFINITION OF HOSPITAL SERVING SIGNIFICANTLY DISPROPORTIONATE NUMBER OF LOW-INCOME PATIENTS OR PATIENTS ENTITLED TO HOSPITAL SERVICES BENEFITS FOR AGED AND DISABLED; IDENTIFICATION

Section 2315(h) of Pub. L. 98–369 provided that: “The Secretary of Health and Human Services shall, prior to December 31, 1984—

“(1) develop and publish a definition of ‘hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of title XVIII of the Social Security Act [part A of this subchapter] for purposes of section 1886(d)(5)(C)(i) of that Act [subsec. (d)(5)(C)(i) of this section], and
“(2) identify those hospitals which meet such definition, and make such identity available to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate.”

**Prospective Payment Wage Index; Studies and Reports to Congress**

Section 2316 of Pub. L. 98-369, as amended by Pub. L. 99-272, title IX, §9103(a)(1), Apr. 7, 1986, 100 Stat. 156, provided that:

“(a) The Secretary of Health and Human Services, in consultation with the Secretary of Labor, shall conduct a study to develop an appropriate index for purposes of adjusting payment amounts under section 1886(d) of the Social Security Act [subsec. (d) of this section] to reflect area differences in average hospital wage levels, as required under paragraphs (2)(H) and (3)(E) of such section [subsec. (d)(2)(H) and (3)(E) of this section], taking into account wage differences of full time and part time workers. The Secretary of Health and Human Services shall report the results of such study to the Congress not later than 30 days after the date of the enactment of this Act [July 18, 1984], including any changes which the Secretary determines to be necessary to provide for an appropriate index.

“(b) The Secretary shall adjust the payment amounts for hospitals for discharges occurring on or after May 1, 1981, to reflect the changes in wage levels the Secretary has promulgated in final regulations (on September 3, 1985) relating to the hospital wage index under section 1886(d)(3)(E) of the Social Security Act [subsec. (d)(3)(E) of this section]. For discharges occurring after September 30, 1986, the Secretary shall provide for such periodic adjustments in the appropriate wage index used under that section as may be necessary, taking into account changes in the wage levels and relative proportions of full-time and part-time workers.

“(c) The Secretary shall conduct a study and report to the Congress on proposed criteria under which, in the case of a hospital that demonstrates to the Secretary in a current fiscal year that the adjustment being made under paragraph (2)(H) or (3)(E) of section 1886(d) of the Social Security Act [subsec. (d)(2)(H) or (3)(E) of this section] for that hospital’s discharges in that fiscal year does not accurately reflect the wage levels in the labor market serving the hospital, the Secretary, to the extent he deems appropriate, would modify such adjustment for that hospital for discharges in the subsequent fiscal year to take into account a difference in payment amounts in that current fiscal year to the hospital that resulted from such inaccuracy.

Section 9103(a)(3) of Pub. L. 99-272 provided that: “The amendment made by paragraph (1) [amending this note] shall be effective as if it had been included in the Deficit Reduction Act of 1984 (Pub. L. 98-369).”

**Different Treatment of Capital-Projects-Related Costs Before and After Implementation of System for Including Such Costs Under Prospectively Determined Payment Rate**

Section 601(a)(3) of Pub. L. 98-21 provided that: “It is the intent of Congress that, in considering the implementation of a system for including capital-related costs under a prospectively determined payment rate for inpatient hospital services, costs related to capital projects for which expenditures are obligated on or after the effective date of the implementation of such a system may or may not be distinguishable and treated differently from costs of projects for which expenditures were obligated before such date.”

**New England Hospitals; Classification as Urban or Rural**

Section 601(g) of Pub. L. 98-21 provided that: “In determining whether a hospital is in an urban or rural area for purposes of section 1886(d) of the Social Security Act [subsec. (d) of this section], the Secretary of Health and Human Services shall classify any hospital located in New England as being located in an urban area if such hospital was classified as being located in an urban area under the Standard Metropolitan Statistical Area system of classification in effect in 1979.”

**Reports, Experiments, and Demonstration Projects Related to Inclusion in Prospective Payment Amounts of Inpatient Hospital Service Capital-Related Costs**

Section 603(a) of title VI of Pub. L. 98-21, as amended by Pub. L. 99-369, div. B, title III, §2317, July 18, 1984, 98 Stat. 1981; Pub. L. 99-509, title IX, §9305(a)(1), Oct. 1, 1986, 100 Stat. 1993; Pub. L. 102-466, title I, §1061(d), Dec. 21, 1995, 109 Stat. 720, directed Secretary of Health and Human Services to report to Congress within 18 months after Apr. 20, 1983, on legislation by which capital-related costs associated with inpatient hospital services could be included within the prospective payment amounts computed under subsec. (d) of this section, further provided that the Secretary was to study and report to Congress on reimbursement of sole community hospitals based on variations in occupancy, on coordination of an information transfer between parts A and B of this subchapter, on treatment of uncompensated care costs and adjustments appropriate for large rural teaching hospitals, and on advisability of having hospitals make cost-of-care information to certain patients, and further provided that the Secretary was to study and report to Congress on a method for including hospitals outside the 50 States and the District of Columbia under a prospective payment system.

**Inapplicability of Coordination of Federal Information Policy to the Collection of Information**

Section 101(b)(2)(B) of Pub. L. 97-248, as amended by Pub. L. 97-448, title III, §308(a)(1), Jan. 12, 1983, 86 Stat. 2468, provided that: “Chapter 35 of title 44, United States Code, shall not apply, until January 1, 1984, to collection of information and information collection requests which the Secretary of Health and Human Services determines to be necessary to carry out the amendments made by this section [amendments by section 101(a) of Pub. L. 97-248, enacting this section and amending section 1969c of this title].”

$§ 1395xx. Payment of provider-based physicians and payment under certain percentage arrangements$
(B) In determining the amount of the payments which may be made with respect to services described in paragraph (1)(B), after apportioning costs as required by subparagraph (A), the Secretary may not recognize as reasonable (in the efficient delivery of health services) such portion of the provider's costs for such services to the extent that such costs exceed the reasonable compensation equivalent for such services. The reasonable compensation equivalent for any service shall be established by the Secretary in regulations.

(C) The Secretary may, upon a showing by a hospital or facility that it is unable to recruit or maintain an adequate number of physicians for the hospital or facility on account of the reimbursement limits established under this subsection, grant exceptions to such reimbursement limits as may be necessary to allow such provider to provide a compensation level sufficient to provide adequate physician services in such hospital or facility.

(b) Prohibition of recognition of payments under certain percentage agreements

(1) Except as provided in paragraph (2), in the case of a provider of services which is paid under this subchapter on a reasonable cost basis, or other basis related to costs that are reasonable, and which has entered into a contract for the purpose of having services furnished for or on behalf of it, the Secretary may not include any cost incurred by the provider under the contract if the amount payable under the contract by the provider for that cost is determined on the basis of a percentage (or other proportion) of the provider's charges, revenues, or claim for reimbursement.

(2) Paragraph (1) shall not apply—

(A) to services furnished by a physician and described in subsection (a)(1)(B) of this section and covered by regulations in effect under subsection (a) of this section, and

(B) under regulations established by the Secretary, where the amount involved under the percentage contract is reasonable and the contract—

(i) is a customary commercial business practice, or

(ii) provides incentives for the efficient and economical operation of the provider of services.


AMENDMENTS

1983—Subsec. (a)(1)(B). Pub. L. 98–21 inserted "or on the bases described in section 1395ww of this title".


EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by 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.

EFFECTIVE DATE OF 1982 AMENDMENT

Section 109(c)(1), (2) of Pub. L. 97–248 provided that:

"(1) The amendments made by this section [amending this section and section 1395xx of this title] shall become effective on the date of the enactment of this Act [Sept. 3, 1982], except that section 1887(b)(1) of the Social Security Act [subsection (b)(1) of this section] shall not apply before October 1, 1982, to services furnished by a physician and described in section 1887(a)(1)(B) of such Act [subsection (a)(1)(B) of this section].

"(2) In the case of a contract with a provider of services entered into prior to the date of the enactment of this Act [Sept. 3, 1982], the amendment made by subsection (a) [amending this section] shall apply to payments under such contract (A) 30 days after the first date (after such date of enactment) the provider of services may unilaterally terminate the contract, or (B) one year after the date of the enactment of this Act, whichever is earlier."

EFFECTIVE DATE OF REGULATIONS

Section 108(b), formerly § 108(c), of Pub. L. 97–248, as redesignated by Pub. L. 97–448, title III, § 309(a)(3), Jan. 12, 1983, 96 Stat. 2408, provided that: "The Secretary of Health and Human Services shall first promulgate regulations to carry out section 1887(a) of the Social Security Act [subsection (a) of this section] not later than October 1, 1982. Such regulations shall be effective on the date of the enactment of this Act [Sept. 3, 1982], the amendment made by subsection (a) [amending this section] shall apply to payments under such contract (A) 30 days after the first date (after such date of enactment) the provider of services may unilaterally terminate the contract, or (B) one year after the date of the enactment of this Act, whichever is earlier."

§ 1395yy. Payment to skilled nursing facilities for routine service costs

(a) Per diem limitations

The Secretary, in determining the amount of the payments which may be made under this subchapter with respect to routine service costs of extended care services shall not recognize as reasonable (in the efficient delivery of health services) per diem costs of such services to the extent that such per diem costs exceed the following per diem limits, except as otherwise provided in this section:

(1) With respect to freestanding skilled nursing facilities located in urban areas, the limit shall be equal to 112 percent of the mean per diem routine service costs for freestanding skilled nursing facilities located in urban areas.

(2) With respect to freestanding skilled nursing facilities located in rural areas, the limit shall be equal to 112 percent of the mean per diem routine service costs for freestanding skilled nursing facilities located in rural areas.

(3) With respect to hospital-based skilled nursing facilities located in urban areas, the limit shall be equal to the sum of the limit for freestanding skilled nursing facilities located in urban areas, plus 50 percent of the amount by which 112 percent of the mean per diem routine service costs for hospital-based skilled nursing facilities located in urban areas exceeds the limit for freestanding skilled nursing facilities located in urban areas.

(4) With respect to hospital-based skilled nursing facilities located in rural areas, the
limit shall be equal to the sum of the limit for freestanding skilled nursing facilities located in rural areas, plus 50 percent of the amount by which 112 percent of the mean per diem routine service costs for hospital-based skilled nursing facilities located in rural areas exceeds the limit for freestanding skilled nursing facilities located in rural areas.

In applying this subsection the Secretary shall make appropriate adjustments to the labor-related portion of the costs based upon an appropriate wage index, and shall, for cost reporting periods beginning on or after October 1, 1992, on or after October 1, 1995, and every 2 years thereafter, provide for an update to the per diem cost limits described in this subsection, except that the limits effective for cost reporting periods beginning on or after October 1, 1997, shall be based on the limits effective for cost reporting periods beginning on or after October 1, 1996.

(b) Excess overhead allocations for hospital-based facilities

With respect to a hospital-based skilled nursing facility, the Secretary may not recognize as reasonable the portion of the cost differences between hospital-based and freestanding skilled nursing facilities attributable to excess overhead allocations.

(c) Adjustments in limitations; publication of data

The Secretary may make adjustments in the limits set forth in subsection (a) of this section with respect to any skilled nursing facility to the extent the Secretary deems appropriate, based upon case mix or circumstances beyond the control of the facility. The Secretary shall publish the data and criteria to be used for purposes of this subsection on an annual basis.

(d) Access to skilled nursing facilities

(1) Subject to subsection (e) of this section, any skilled nursing facility may choose to be paid under this subsection on the basis of a prospective payment for all routine service 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) and capital-related costs of extended care services provided in a cost reporting period if such facility had, in the preceding cost reporting period, fewer than 1,500 patient days with respect to which payments were made under this subsection, except that the limits effective for cost reporting periods beginning on or after October 1, 1997, shall be based on the limits effective for cost reporting periods beginning on or after October 1, 1996.

(2)(A) The amount of the payment under this section shall be determined on a per diem basis.

(B) Subject to the limitations of subparagraph (C), for skilled nursing facilities located—

(i) in an urban area, the amount shall be equal to 105 percent of the mean of the per diem reasonable routine service and capital-related costs of extended care services for skilled nursing facilities in urban areas within the same region, determined without regard to the limitations of subsection (a) of this section and adjusted for different area wage levels, and

(ii) in a rural area the amount shall be equal to 105 percent of the mean of the per diem reasonable routine service and capital-related costs of extended care services for skilled nursing facilities in rural areas within the same region, determined without regard to the limitations of subsection (a) of this section and adjusted for different area wage levels.

(C) The per diem amounts determined under subparagraph (B) shall not exceed the limit on routine service costs determined under subsection (a) of this section with respect to the facility, adjusted to take into account average capital-related costs with respect to the type and location of the facility.

(3) For purposes of this subsection, urban and rural areas shall be determined in the same manner as for purposes of subsection (a) of this section, and the term “region” shall have the same meaning as under section 1395ww(d)(2)(D) of this title.

(4) The Secretary shall establish the prospective payment amounts for cost reporting periods beginning in a fiscal year at least 90 days prior to the beginning of such fiscal year, on the basis of the most recent data available for a 12-month period. A skilled nursing facility must notify the Secretary of its intention to be paid pursuant to this subsection for a cost reporting period no later than 30 days before the beginning of that period.

(5) The Secretary shall provide for a simplified cost report to be filed by facilities being paid pursuant to this subsection, which shall require only the cost information necessary for determining prospective payment amounts pursuant to paragraph (2) and reasonable costs of ancillary services.

(6) In lieu of payment on a cost basis for ancillary services provided by a facility which is being paid pursuant to this subsection, the Secretary may pay for such ancillary services on a reasonable charge basis if the Secretary determines that such payment basis will provide an equitable level of reimbursement and will ease the reporting burden of the facility.

(7) In computing the rates of payment to be made under this subsection, there shall be taken into account the costs described in the last sentence of section 1395x(v)(1)(E) of this title (relating to compliance with nursing facility requirements and of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

(e) Prospective payment

(1) Payment provision

Notwithstanding any other provision of this subchapter, subject to paragraphs (7), (11), and (12), the amount of the payment for all costs (as defined in paragraph (2)(B)) of covered skilled nursing facility services (as defined in
paragraph (2)(A)) for each day of such services furnished—

(A) in a cost reporting period during the transition period (as defined in paragraph (2)(E)), is equal to the sum of—

(i) the non-Federal percentage of the facility-specific per diem rate (computed under paragraph (3)), and

(ii) the Federal percentage of the adjusted Federal per diem rate (determined under paragraph (4)) applicable to the facility; and

(B) after the transition period is equal to the adjusted Federal per diem rate applicable to the facility.

(2) Definitions

For purposes of this subsection:

(A) Covered skilled nursing facility services

(i) In general

The term “covered skilled nursing facility services”—

(I) means post-hospital extended care services as defined in section 1395x(i) of this title for which benefits are provided under part A of this subchapter; and

(II) includes all items and services other than items and services described in clauses (ii), (iii), and (iv) for which payment may be made under part B of this subchapter and which are furnished to an individual who is a resident of a skilled nursing facility during the period in which the individual is provided covered post-hospital extended care services.

(ii) Services excluded

Services described in this clause are physicians’ services, services described by clauses (i) and (ii) of section 1395x(s)(2)(K) of this title, certified nurse-midwife services, qualified psychologist services, services of a certified registered nurse anesthetist, items and services described in subparagraphs (F) and (O) of section 1395x(s)(2) of this title, telehealth services furnished under section 1395m(m)(4)(C)(II)(VII) of this title, and, only with respect to services furnished during 1999, the transportation costs of electrocardiogram equipment for electrocardiogram test services (HCPCS Code 92076). Services described in this clause do not include any physical, occupational, or speech-language therapy services regardless of whether or not the services are furnished by, or under the supervision of, a physician or other health care professional.

(iii) Exclusion of certain additional items and services

Items and services described in this clause are the following:

(I) Ambulance services furnished to an individual in conjunction with renal dialysis services described in section 1395x(s)(2)(F) of this title.

(II) Chemotherapy items (identified as of July 1, 1999, by HCPCS codes J9000–J9020; J9040–J9151; J9170–J9185; J9200–J9201; J9206–J9208; J9211; J9230–J9245; and J9265–J9600 (and as subsequently modified by the Secretary)) and any additional chemotherapy items identified by the Secretary.

(III) Chemotherapy administration services (identified as of July 1, 1999, by HCPCS codes 36260–36262; 36489; 36530–36535; 36640; 36823; and 96405–96542 (and as subsequently modified by the Secretary)) and any additional chemotherapy administration services identified by the Secretary.

(IV) Radioisotope services (identified as of July 1, 1999, by HCPCS codes 79030–79440 (and as subsequently modified by the Secretary)) and any additional radioisotope services identified by the Secretary.

(V) Customized prosthetic devices (commonly known as artificial limbs or components of artificial limbs) under the following HCPCS codes (as of July 1, 1999 (and as subsequently modified by the Secretary)), and any additional customized prosthetic devices identified by the Secretary, if delivered to an inpatient for use during the stay in the skilled nursing facility and intended to be used by the individual after discharge from the facility: L5050–L5340; L5500–L5611; L6050–L6370; L6400–L6880; L6920–L7274; and L7362–7366.

(iv) Exclusion of certain rural health clinic and federally qualified health center services

Services described in this clause are—

(I) rural health clinic services (as defined in paragraph (1) of section 1395x(aa) of this title); and

(II) federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were furnished by an individual not affiliated with a rural health clinic or a federally qualified health center.

(B) All costs

The term “all costs” means routine service costs, ancillary costs, and capital-related costs of covered skilled nursing facility services, but does not include costs associated with approved educational activities.

(C) Non-Federal percentage; Federal percentage

For—

(i) the first cost reporting period (as defined in subparagraph (D)) of a facility, the “non-Federal percentage” is 75 percent and the “Federal percentage” is 25 percent;

(ii) the next cost reporting period of such facility, the “non-Federal percentage” is 50 percent and the “Federal percentage” is 50 percent; and

(iii) the subsequent cost reporting period of such facility, the “non-Federal percent-
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age’’ is 25 percent and the ‘‘Federal percentage’’ is 75 percent.

(D) First cost reporting period

The term ‘‘first cost reporting period’’ means, with respect to a skilled nursing facility, the first cost reporting period of the facility beginning on or after July 1, 1998.

(E) Transition period

(i) In general

The term ‘‘transition period’’ means, with respect to a skilled nursing facility, the 3 cost reporting periods of the facility beginning with the first cost reporting period.

(ii) Treatment of new skilled nursing facilities

In the case of a skilled nursing facility that first received payment for services under this subchapter on or after October 1, 1995, payment for such services shall be made under this subsection as if all services were furnished after the transition period.

(3) Determination of facility specific per diem rates

The Secretary shall determine a facility-specific per diem rate for each skilled nursing facility not described in paragraph (2)(E)(ii) for a cost reporting period as follows:

(A) Determining base payments

The Secretary shall determine, on a per diem basis, the total of—

(i) the allowable costs of extended care services for the facility for cost reporting periods beginning in fiscal year 1995, including costs associated with facilities described in subsection (d) of this section, with appropriate adjustments (as determined by the Secretary) to non-settled cost reports or, in the case of a facility participating in the Nursing Home Case-Mix and Quality Demonstration (RUGS–III), the RUGS–III rate received by the facility during the cost reporting period beginning in 1997, and

(ii) an estimate of the amounts that would be payable under part B of this subchapter (disregarding any applicable deductibles, coinsurance, and copayments) for covered skilled nursing facility services described in paragraph (2)(A)(i)(II) furnished during the applicable cost reporting period described in clause (i) to an individual who is a resident of the facility, regardless of whether or not the payment was made to the facility or to another entity.

In making appropriate adjustments under clause (i), the Secretary shall take into account exceptions and shall take into account exemptions but, with respect to exemptions, only to the extent that routine costs do not exceed 150 percent of the routine cost limits otherwise applicable but for the exemption.

(B) Update to first cost reporting period

The Secretary shall update the amount determined under subparagraph (A), for each cost reporting period after the applicable cost reporting period described in subparagraph (A)(i) and up to the first cost reporting period by a factor equal to the skilled nursing facility market basket percentage increase minus 1.0 percentage point.

(C) Updating to applicable cost reporting period

The Secretary shall update the amount determined under subparagraph (B) for each cost reporting period beginning with the first cost reporting period and up to and including the cost reporting period involved by a factor equal to the facility-specific update factor.

(D) Facility-specific update factor

For purposes of this paragraph, the ‘‘facility-specific update factor’’ for cost reporting periods beginning during—

(i) during each of fiscal years 1998 and 1999, is equal to the skilled nursing facility market basket percentage increase for such fiscal year minus 1 percentage point, and

(ii) during each subsequent fiscal year is equal to the skilled nursing facility market basket percentage increase for such fiscal year.

(4) Federal per diem rate

(A) Determination of historical per diem for facilities

For each skilled nursing facility that received payments for post-hospital extended care services during a cost reporting period beginning in fiscal year 1995 and that was subject to (and not exempted from) the per diem limits referred to in paragraph (1) or (2) of subsection (a) of this section (and facilities described in subsection (d) of this section), the Secretary shall estimate, on a per diem basis for such cost reporting period, the total of—

(i) the allowable costs of extended care services (excluding exceptions payments) for the facility for cost reporting periods beginning in 1995 with appropriate adjustments (as determined by the Secretary) to non-settled cost reports, and

(ii) an estimate of the amounts that would be payable under part B of this subchapter (disregarding any applicable deductibles, coinsurance, and copayments) for covered skilled nursing facility services described in paragraph (2)(A)(i)(II) furnished during such period to an individual who is a resident of the facility, regardless of whether or not the payment was made to the facility or to another entity.

(B) Update to first fiscal year

The Secretary shall update the amount determined under subparagraph (A), for each cost reporting period after the cost reporting period described in subparagraph (A)(i) and up to the first cost reporting period by a factor equal to the skilled nursing facility market basket percentage increase reduced (on an annualized basis) by 1 percentage point.
(C) Computation of standardized per diem rate

The Secretary shall standardize the amount updated under subparagraph (B) for each facility by—

(i) adjusting for variations among facilities by area in the average facility wage level per diem, and

(ii) adjusting for variations in case mix per diem among facilities.

(D) Computation of weighted average per diem rates

(i) All facilities

The Secretary shall compute a weighted average per diem rate for all facilities by computing an average of the standardized amounts computed under subparagraph (C), weighted for each facility by the number of days of extended care services furnished during the cost reporting period referred to in subparagraph (A).

(ii) Freestanding facilities

The Secretary shall compute a weighted average per diem rate for freestanding facilities by computing an average of the standardized amounts computed under subparagraph (C) only for such facilities, weighted for each facility by the number of days of extended care services furnished during the cost reporting period referred to in subparagraph (A).

(iii) Separate computation

The Secretary may compute and apply such averages separately for facilities located in urban and rural areas (as defined in section 1395ww(d)(2)(D) of this title).

(E) Updating

(i) Initial period

For the initial period beginning on July 1, 1998, and ending on September 30, 1999, the Secretary shall compute for skilled nursing facilities an unadjusted Federal per diem rate equal to the average of the weighted average per diem rates computed under clauses (i) and (ii) of subparagraph (D), increased by skilled nursing facility market basket percentage change for such period minus 1 percentage point.

(ii) Subsequent fiscal years

The Secretary shall compute an unadjusted Federal per diem rate equal to the Federal per diem rate computed under this subparagraph—

(I) for fiscal year 2000, the rate computed for the initial period described in clause (i), increased by the skilled nursing facility market basket percentage change for the initial period minus 1 percentage point;

(II) for fiscal year 2001, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year;

(III) for each of fiscal years 2002 and 2003, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved minus 0.5 percentage points; and

(IV) for each subsequent fiscal year, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved.

(F) Adjustment for case mix creep

Insofar as the Secretary determines that the adjustments under subparagraph (G)(i) for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year that are a result of changes in the coding or classification of residents that do not reflect real changes in case mix, the Secretary may adjust unadjusted Federal per diem rates for subsequent fiscal years so as to eliminate the effect of such coding or classification changes.

(G) Determination of Federal rate

The Secretary shall compute for each skilled nursing facility for each fiscal year (beginning with the initial period described in subparagraph (E)(i)) an adjusted Federal per diem rate equal to the unadjusted Federal per diem rate determined under subparagraph (E), as adjusted under subparagraph (F), and as further adjusted as follows:

(i) Adjustment for case mix

The Secretary shall provide for an appropriate adjustment to account for case mix. Such adjustment shall be based on a resident classification system, established by the Secretary, that accounts for the relative resource utilization of different patient types. The case mix adjustment shall be based on resident assessment data and other data that the Secretary considers appropriate.

(ii) Adjustment for geographic variations in labor costs

The Secretary shall adjust the portion of such per diem rate attributable to wages and wage-related costs for the area in which the facility is located compared to the national average of such costs using an appropriate wage index as determined by the Secretary. Such adjustment shall be done in a manner that does not result in aggregate payments under this subsection that are greater or less than those that would otherwise be made if such adjustment had not been made.

(iii) Adjustment for exclusion of certain additional items and services

The Secretary shall provide for an appropriate proportional reduction in payments so that beginning with fiscal year 2001, the aggregate amount of such reductions is equal to the aggregate increase in payments attributable to the exclusion effected under clause (iii) of paragraph (2)(A).
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(5) Skilled nursing facility market basket index and percentage

For purposes of this subsection:
(A) Skilled nursing facility market basket index

The Secretary shall establish a skilled nursing facility market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered skilled nursing facility services.

(B) Skilled nursing facility market basket percentage

(i) In general

Subject to clause (ii), the term “skilled nursing facility market basket percentage” means, for a fiscal year or other annual period and as calculated by the Secretary, the percentage change in the skilled nursing facility market basket index (established under subparagraph (A)) from the midpoint of the prior fiscal year (or period) to the midpoint of the fiscal year (or other period) involved.

(ii) Adjustment

For fiscal year 2012 and each subsequent fiscal year, after determining the percentage described in clause (i), the Secretary shall reduce such percentage by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title. The application of the preceding sentence may result in such percentage being less than 0.0 for a fiscal year, and may result in payment rates under this subsection for a fiscal year being less than such payment rates for the preceding fiscal year.

(6) Submission of resident assessment data

A skilled nursing facility, or a facility described in paragraph (7)(B), shall provide the Secretary, in a manner and within the time-frames prescribed by the Secretary, the resident assessment data necessary to develop and implement the rates under this subsection. For purposes of meeting such requirement, a skilled nursing facility, or a facility described in paragraph (7), may submit the resident assessment data required under section 1395i–3(b)(3) of this title, using the standard instrument designated by the State under section 1395i–3(e)(5) of this title.

(7) Treatment of medicare swing bed hospitals

(A) Transition

Subject to subparagraph (C), the Secretary shall determine an appropriate manner in which to apply this subsection to the facilities described in paragraph (B) (other than critical access hospitals), taking into account the purposes of this subsection, and shall provide that at the end of the transition period (as defined in paragraph (2)(E)) such facilities shall be paid only under this subsection. Payment shall not be made under this subsection to such facilities for cost reporting periods beginning before such date (not earlier than July 1, 1999) as the Secretary specifies.

(B) Facilities described

The facilities described in this subparagraph are facilities that have in effect an agreement described in section 1395tt of this title.

(C) Exemption from PPS of swing-bed services furnished in critical access hospitals

The prospective payment system established under this subsection shall not apply to services furnished by a critical access hospital pursuant to an agreement under section 1395tt of this title.

(8) Limitation on review

There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise of—

(A) the establishment of Federal per diem rates under paragraph (4), including the computation of the standardized per diem rates under paragraph (4)(C), adjustments and corrections for case mix under paragraphs (4)(F) and (4)(G)(I), adjustments for variations in labor-related costs under paragraph (4)(G)(II), and adjustments under paragraph (4)(G)(II);

(B) the establishment of facility specific rates before July 1, 1999 (except any determination of costs paid under part A of this subchapter); and

(C) the establishment of transitional amounts under paragraph (7).

(9) Payment for certain services

In the case of an item or service furnished to a resident of a skilled nursing facility or a part of a facility that includes a skilled nursing facility (as determined under regulations) for which payment would (but for this paragraph) be made under part B of this subchapter in an amount determined in accordance with section 1395(a)(2)(B) of this title, the amount of the payment under such part shall be the amount provided under the fee schedule for such item or service. In the case of an item or service described in clause (iii) of paragraph (2)(A) that would be payable under part A of this subchapter but for the exclusion of such item or service under such clause, pay-
(11) Permitting facilities to waive 3-year transition
Notwithstanding paragraph (1)(A), a facility may elect to have the amount of the payment for all costs of covered skilled nursing facility services for each day of such services furnished in cost reporting periods beginning no earlier than 30 days before the date of such election determined pursuant to paragraph (1)(B).

(12) Adjustment for residents with AIDS
(A) In general
Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune deficiency syndrome (AIDS), the per diem amount of payment otherwise applicable (determined without regard to any increase under section 101 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, or under section 314(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000), shall be increased by 128 percent to reflect increased costs associated with such residents.

(B) Sunset
Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.

(f) Reporting of direct care expenditures
(1) In general
For cost reports submitted under this subchapter for cost reporting periods beginning on or after the date that is 2 years after March 23, 2010, skilled nursing facilities shall separately report expenditures for wages and benefits for direct care staff (breaking out at a minimum) registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

(2) Modification of form
The Secretary, in consultation with private sector accountants experienced with Medicare and Medicaid nursing facility home cost reports, shall redesign such reports to meet the requirement of paragraph (1) not later than 1 year after March 23, 2010.

(3) Categorization by functional accounts
Not later than 30 months after March 23, 2010, the Secretary, working in consultation with the Medicare Payment Advisory Commission, the Medicaid and CHIP Payment and Access Commission, the Inspector General of the Department of Health and Human Services, and other expert parties the Secretary determines appropriate, shall take the expenditures listed on cost reports, as modified under paragraph (1), submitted by skilled nursing facilities and categorize such expenditures, regardless of any source of payment for such expenditures, for each skilled nursing facility into the following functional accounts on an annual basis:

(A) Spending on direct care services (including nursing, therapy, and medical services).

(B) Spending on indirect care (including housekeeping and dietary services).

(C) Capital assets (including building and land costs).

(D) Administrative services costs.

(4) Availability of information submitted
The Secretary shall establish procedures to make information on expenditures submitted under this subsection readily available to interested parties upon request, subject to such requirements as the Secretary may specify under the procedures established under this paragraph.


REFERENCES IN TEXT
Parts A and B of this subchapter, referred to in subsec. (e), are classified to section 1395c et seq. and section 1395yy et seq., respectively, of this title.

Section 314(a) of Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, referred to in subsec. (e)(12)(A), in section 1a(a)(6) [title III, §1395t of this title].

Subsection (e)(7)(A) of Pub. L. 105–33, §4433, substituted “subject to clause (ii), the Secretary shall update the amount determined under subparagraph (A), for each cost reporting period after the cost reporting period described in subparagraph (A)(i) and up to the first cost reporting period by a factor equal to the skilled nursing facility market basket percentage increase minus 1 percentage point.”

Section 314(a)(1)(B), and subject to paragraphs (7), (11), and (12) for “subject to paragraphs (7), (11), and (12)” in introductory provisions.

Subsection (e)(9), (10). Pub. L. 105–33, §4433, added pars. (9) and (10).

1993—Subsec. (a). Pub. L. 103–66, §13530(a)(3)(A), substituted “Secretary may not recognize” for “Secretary shall recognize” and a period for “(as determined by the Secretary) resulting from the reimbursement principles under this subchapter, notwithstanding the limits set forth in paragraph (3) or (4) of subsection (a) of this section.”

1990—Subsec. (a). Pub. L. 101–508, §4088(e)(2), struck out period at end and inserted “, and shall, for cost reporting periods beginning on or after October 1, 1992 and every 2 years thereafter, provide for an update to the per diem cost limits described in this subsection.”

Subsection (d)(7)(B). Pub. L. 105–113, §1000(a)(6) [title I, §103(b)(2)], substituted “subject to clause (ii), the Secretary shall update the amount determined under subpart A of this subchapter, notwithstanding the limits set forth in paragraph (3) or (4) of subsection (a) of this section.”


Subsection (d)(1). Pub. L. 101–508, §4088(b)(2)(A)(ii), substituted “(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) and capital-related costs for “(and capital-related costs)”.

MENDMENTS


Subsection (e)(7)(B). Pub. L. 105–33, §4431, substituted “described in this subsection, except that the limits effective for cost reporting periods beginning on or after October 1, 1997, shall be based on the limits effective for cost reporting periods beginning on or after October 1, 1996,” for “described in this subsection” at end.


Subsection (e)(2)(A)(ii). Pub. L. 105–33, §4431, substituted “subject to clause (ii), the Secretary shall update the amount determined under subpart A of this subchapter, notwithstanding the limits set forth in paragraph (3) or (4) of subsection (a) of this section.”

1993—Subsec. (a). Pub. L. 103–66, §13530(a)(3)(A), substituted “Secretary may not recognize” for “Secretary shall recognize” and a period for “(as determined by the Secretary) resulting from the reimbursement principles under this subchapter, notwithstanding the limits set forth in paragraph (3) or (4) of subsection (a) of this section.”

1990—Subsec. (a). Pub. L. 101–508, §4089(b)(2), struck out period at end and inserted “, and shall, for cost reporting periods beginning on or after October 1, 1992 and every 2 years thereafter, provide for an update to the per diem cost limits described in this subsection.”

Subsection (d)(1). Pub. L. 101–508, §4089(b)(2)(A)(ii), substituted “(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) and capital-related costs for “(and capital-related costs)”.

ERTAIN DEMONSTRATION PROJECTS—In the case of an item or service described in clause (ii) of paragraph 2(A) that would be payable under part A of this subchapter but for the exclusion of such item or service under such clause, payment shall be made for the item or service, in an amount otherwise determined under part B of this subchapter for such item or service, from the Federal Hospital Insurance Trust Fund under section 1395i of this title (rather than from the Federal Supplementary Medical Insurance Trust Fund under section 1395f of this title).
1986—Subsec. (b). Pub. L. 99–272, §9219(b)(1)(C), sub-
stituted “notwithstanding” for “notwithstanding”.
Subsec. (c). Pub. L. 99–272, §9219(b), inserted provision
requiring the Secretary to publish data and criteria to
be used for purposes of this subsection on an annual ba-

Subsec. (d)(1). Pub. L. 99–514, §1895b(b)(7)(A), sub-
stituted “cost reporting period” for “fiscal year” in first
places.
Subsec. (d)(4). Pub. L. 99–514, §1895b(b)(7)(B), sub-
stituted “cost reporting periods beginning in a fiscal
year” for “each fiscal year” and “cost reporting period
no later than 30 days before the beginning of that pe-
riod” for “fiscal year within 60 days after the Secretary
establishes the final prospective payment amounts for
such fiscal year”.

Effective Date of 2008 Amendment
Amendment by Pub. L. 110–275 applicable to services
furnished on or after Jan. 1, 2009, see section 149(c) of
Pub. L. 110–275, set out as a note under section 1359m of
this title.

Effective Date of 2003 Amendment
2271, provided that: “The amendments made by sub-
section (a) [amending this section] shall apply to serv-
ces furnished on or after January 1, 2005.”
2299, provided that: “The amendment made by para-
graph (1) [probably should be “subsection (a)”], amend-
ing this section] shall apply to services furnished on or
after October 1, 2004.”

Effective Date of 2000 Amendment
Amendment by section 1(a)(6) [title II, §203(a)] of
Pub. L. 106–554 applicable to cost reporting periods be-
ginning on or after Dec. 21, 2001, see section 1(a)(6) [ti-
el IV, §203(c)] of Pub. L. 106–554, set out as a note un-
der section 1385t of this title.

Effective Date of 1999 Amendment
Pub. L. 106–113, div. B, §1000(a)(6) [title I, §102(b)],
Nov. 29, 1999, 113 Stat. 1356, 1301A–325, provided that:
“The amendments made by subsection (a) [amending
this section] shall apply to elections made on or after
December 15, 1999, except that no election shall be ef-
fective under such amendments for a cost reporting pe-
riod beginning before January 1, 2000.”
Pub. L. 106–113, div. B, §1000(a)(6) [title I, §103(c)],
Nov. 29, 1999, 113 Stat. 1356, 1301A–326, provided that:
“The amendments made by subsection (a) [amending
this section] shall apply to payments made for items
and services furnished on or after April 1, 2000.”
Pub. L. 106–113, div. B, §1000(a)(6) [title I, §104(b)],
Nov. 29, 1999, 113 Stat. 1356, 1301A–327, provided that:
“The amendments made by subsection (a) [amending
this section] shall be effective as if included in the en-
actment of section 452(a) of BBA [the Balanced Budget
Pub. L. 106–113, div. B, §1000(a)(6) [title I, §105(b)],
Nov. 29, 1999, 113 Stat. 1356, 1301A–328, provided that:
“The amendments made by subsection (a) [amending
this section] begin after the date of the enactment of this
Act and ending on September 30, 2001, and apply to
skilled nursing facilities furnishing covered skilled
nursing facility services on the date of the en-
actment of this Act for which payment is made under
title XVIII of the Social Security Act [this sub-
chapter].”
Amendment by section 1000(a)(6) [title III, §321(c)(1),
(k)(18)] of Pub. L. 106–113 effective as if included in the
except as otherwise provided, see section 1385d of Pub. L. 105–33, set out as a
note under section 1385d of this title.

Effective Date of 1997 Amendment
Amendment by section 4423(a), (b)(3), (5)(H) of Pub. L.
105–33 effective for cost reporting periods beginning on
or after July 1, 1998, except that amendment by section
4423(b) applicable to items and services furnished on or
after July 1, 1998, see section 4423(d) of Pub. L. 105–33,
set out as a note under section 1385i–3 of this title.
Amendment by section 4511(a)(2)(E) of Pub. L. 105–33
applicable with respect to services furnished and sup-
plies provided on and after Jan. 1, 1998, see section
4511(e) of Pub. L. 105–33, set out as a note under section
1385c of this title.

Effective Date of 1993 Amendment
Section 13503(a)(3)(B) of Pub. L. 103–66 provided that:
“The amendments made by subparagraph (A) [amend-
ing this section] shall apply to cost reporting periods
beginning on or after October 1, 1992.”

Effective Date of 1990 Amendment
Section 400e(c)(3) of Pub. L. 101–508 provided that:
“The amendments made by paragraphs (1) and (2)
[amending this section and provisions set out as a note
below] shall take effect as if included in the enactment
L. 101–239].”
Amendment by section 400e(b)(2)(A)(i) of Pub. L. 101–508
effective as if included in the enactment of the Omnibus
Budget Reconciliation Act of 1987, Pub. L. 100–203, see section 400e(b)(2)(A)(ii) of

Effective Date of 1987 Amendment
Amendment by Pub. L. 100–203 applicable to services
furnished on or after Oct. 1, 1990, without regard to
whether regulations implementing such amendment are
promulgated by such date, except as otherwise spec-
fically provided in section 1385i–3 of this title, see sec-
section 430(a) of Pub. L. 100–203, as amended, set out as an
Effective Date note under section 1385i–3 of this title.

Effective Date of 1986 Amendments
Section 1385(b)(7)(D) of Pub. L. 99–514 provided that:
“The amendments made by subparagraphs (A) and (B)
[amending this section] apply to cost reporting periods
beginning on or after October 1, 1986.
Amendment by section 9219(b)(1)(C) of Pub. L. 99–272
effective as if originally included in the Deficit Reduction
Act of 1984, Pub. L. 99–369, see section 9219(b)(1)(D) of
Pub. L. 99–272, set out as a note under section 1385u of
this title.
Section 912(d) of Pub. L. 99–272, as amended by Pub.
L. 99–514, title XVIII, §1895(b)(7)(C), Oct. 22, 1986, 100
Stat. 2933, provided that:
“(1) The amendment made by subsection (a) [amend-
ing this section] shall apply to cost reporting periods
beginning on or after October 1, 1986.
“(2) The amendment made by subsection (b) [amend-
ing this section] shall become effective on the date of
the enactment of this Act [Apr. 7, 1986].”

Effective Date
Section 2319(c) of Pub. L. 98–369 provided that: “The
amendments made by subsections (a) [amending
section 1385u of this title] and (b) [enacting this section]
shall apply to cost reporting periods beginning on
or after July 1, 1984.”

Study on portable diagnostic ultrasound services for beneficiaries in skilled nursing facilities
2300, directed the Comptroller General of the United
States for a study of portable diagnostic ultrasound
services furnished to Medicare beneficiaries in skilled
nursing facilities and to submit to Congress a report on
the study not later than 2 years after Dec. 8, 2003.
SPECIAL RULE FOR PAYMENT FOR FISCAL YEAR 2001

Pub. L. 106-554, §1(a)(6) [title III, §311(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-497, provided that: "Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for covered skilled nursing facility services under section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)) for fiscal year 2001, the Federal per diem rate referred to in paragraph (4)(E)(ii) of such section—

‘‘(1) for the period beginning on October 1, 2000, and ending on March 31, 2001, shall be the rate determined in accordance with the law as in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]; and

‘‘(2) for the period beginning on April 1, 2001, and ending on September 30, 2001, shall be the rate that would have been determined under such section if ‘plus 1 percentage point’ had been substituted for ‘minus 1 percentage point’ under subclause (II) of such paragraph (as in effect on the day before the date of the enactment of this Act)."

Pub. L. 106-554, §1(a)(6) [title V, §547(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-553, provided that: "The payment increase provided under section 311(b)(2) (set out as a note above) (relating to covered skilled nursing facility services) shall not apply to services furnished after fiscal year 2001 and shall not be taken into account in calculating the payment amounts applicable for services furnished after such fiscal year."

GAO REPORT ON ADEQUACY OF SNF PAYMENT RATES

Pub. L. 106-554, §1(a)(6) [title III, §311(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A-498, provided that: "Not later than July 1, 2002, the Comptroller General of the United States shall submit to Congress a report on the adequacy of Medicare payment rates to skilled nursing facilities and the extent to which Medicare contributes to the financial viability of such facilities. Such report shall take into account the role of private payors, Medicaid, and case mix on the financial performance of these facilities, and shall include an analysis (by specific RUG classification) of the number and characteristics of such facilities."

HCFA STUDY OF CLASSIFICATION SYSTEMS FOR SNF RESIDENTS

Pub. L. 106-554, §1(a)(6) [title III, §311(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A-498, provided that: "(1) STUDY.—The Secretary of Health and Human Services shall conduct a study of the different systems for categorizing patients in Medicare skilled nursing facilities in a manner that accounts for the relative resource utilization of different patient types.

‘‘(2) REPORT.—Not later than January 1, 2005, the Secretary shall submit to Congress a report on the study conducted under subsection (a). Such report shall include such recommendations regarding changes in law as may be appropriate."

GAO AUDIT OF NURSING STAFF RATIOS

Pub. L. 106-554, §1(a)(6) [title III, §312(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-498, provided that: "(1) AUDIT.—The Comptroller General of the United States shall conduct an audit of nursing staffing ratios in a representative sample of Medicare skilled nursing facilities. Such sample shall cover selected States and shall include broad representation with respect to size, ownership, location, and Medicare volume. Such audit shall include an examination of payroll records and Medicaid cost reports of individual facilities.

‘‘(2) REPORT.—Not later than August 1, 2002, the Comptroller General shall submit to Congress a report on the audits conducted under paragraph (1). Such report shall include an assessment of the impact of the increased payments under this subtitle [subtitle B, §§311-315, of title III of §1(a)(6) of Pub. L. 106-554, amending this section and sections 1395u, 1395y, and 1395cc of this title and enacting provisions set out as notes under this section and section 1395u of this title] on increased nursing staffing ratios and shall make recommendations as to whether increased payments under subsection (a) [114 Stat. 2763A-498] should be continued."

OVERSIGHT

Pub. L. 106-554, §1(a)(6) [title III, §313(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A-499, provided that: "The Secretary of Health and Human Services, through the Office of the Inspector General in the Department of Health and Human Services or otherwise, shall monitor payments made under part B of the title XVIII of the Social Security Act (part B of this subchapter) for items and services furnished to residents of skilled nursing facilities during a time in which the residents are not being provided Medicare covered post-hospital extended care services to ensure that there is not duplicate billing for services or excessive services provided."

ESTABLISHMENT OF PROCESS FOR GEOGRAPHIC RECLASSIFICATION

Pub. L. 106-554, §1(a)(6) [title III, §315], Dec. 21, 2000, 114 Stat. 2763, 2763A-500, provided that: "(a) IN GENERAL.—The Secretary of Health and Human Services may establish a procedure for the geographic reclassification of a skilled nursing facility for purposes of payment for covered skilled nursing facility services under the prospective payment system established under section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)). Such procedure may be based upon the method for geographic reclassifications for inpatient hospitals established under section 1886(d)(10) of the Social Security Act (42 U.S.C. 1395ww(d)(10)).

‘‘(b) REQUIREMENT FOR SKILLED NURSING FACILITY WAGE DATA.—In no case may the Secretary implement the procedure under subsection (a) before such time as the Secretary has collected data necessary to establish an area wage index for skilled nursing facilities based on wage data from such facilities.

REPORT TO CONGRESS

Pub. L. 106-113, div. B, §1000(a)(6) [title I, §105(c)], Nov. 29, 1999, 113 Stat. 1356, 1351A-328, provided that: "Not later than March 1, 2001, the Secretary of Health and Human Services shall assess the resource use of patients of skilled nursing facilities furnishing services under the Medicare program who are immunocompromised secondary to an infectious disease, with specific diagnoses as specified by the Secretary (under paragraph (12)(C), as added by subsection (a), of section 1395y of this title), to determine whether any permanent adjustments are needed to the RUGs to take into account the resource uses and costs of these patients."

MEDICAL REVIEW PROCESS

Section 4432(c) of Pub. L. 105-33 provided that: "In order to ensure that Medicare beneficiaries are furnished appropriate services in skilled nursing facilities, the Secretary of Health and Human Services shall establish and implement a thorough medical review process to examine the effects of the amendments made by this section (amending this section and sections 1395k-3, 1395k, 1395l, 1395u, 1395x, 1395y, 1395cc, and 1395tt of this title) on the quality of covered skilled nursing facility services furnished to Medicare beneficiaries. In developing such a medical review process, the Secretary shall place a particular emphasis on the quality of nonroutine covered services and physicians' services for which payment is made under title XVIII of the Social Security Act (this subchapter)."

CONSTRUCTION OF WAGE INDEX FOR SKILLED NURSING FACILITIES

Pub. L. 106-432, title I, §106(a), Oct. 31, 1994, 108 Stat. 4405, provided that: "Not later than 1 year after the date of the enactment of this Act [Oct. 31, 1994], the Secretary of Health and Human Services shall begin to
collect data on employee compensation and paid hours of employment in skilled nursing facilities for the purpose of constructing a skilled nursing facility wage index adjustment to the routine service cost limits required under section 1888(a)(4) of the Social Security Act [subsec. (a)(4) of this section]."

No Change in Limits on Per Diem Service Costs for Extended Care Services for Fiscal Years 1994 and 1995

Section 13003(a)(1) of Pub. L. 101-66 provided that: "The Secretary of Health and Human Services may not provide for any change in the limits on per diem routine service costs for extended care services under section 1888 of the Social Security Act [this section] for cost reporting periods beginning during fiscal years 1994 and 1995, except as may be necessary to take into account the amendments made by paragraph (3)(A) [amending this section]. The effect of the preceding sentence shall not be considered by the Secretary in making adjustments pursuant to section 1888(c) of such Act to the payment limits for such services during such fiscal years."

No Change in Prospective Payments for Services Furnished During Fiscal Years 1994 and 1995

Section 13003(b) of Pub. L. 101-66 provided that: "The Secretary of Health and Human Services may not change the amount of any prospective payment made to a skilled nursing facility under section 1888(d) of the Social Security Act [subsec. (d) of this section] for services furnished during cost reporting periods beginning during fiscal years 1994 and 1995, except as may be necessary to take into account the amendments made by subsection (c)(1)(A) [amending this section]."

Prospective Payment System for Skilled Nursing Facility Services

Section 4008(b) of Pub. L. 101-508 provided that: "(1) DEVELOPMENT OF PROPOSAL.—The Secretary of Health and Human Services shall develop a proposal to modify the current system under which skilled nursing facilities receive payment for extended care services under part A [part A of this subchapter] of the medicare program or a proposal to replace such system with a system under which such payments would be made on the basis of prospectively determined rates. In developing any proposal under this paragraph to replace the current system with a prospective payment system, the Secretary shall—"

(a) take into consideration the need to provide for appropriate limits on increases in expenditures under the medicare program without jeopardizing access to extended care services for individuals unable to care for themselves;

(b) provide for adjustments to prospectively determined rates to account for changes in a facility's case mix, volume of cases, and the development of new technologies and standards of medical practice;

(c) take into consideration the need to increase the payment otherwise made under such system in the case of services provided to patients whose length of stay or costs of treatment greatly exceed the length of stay or cost of treatment provided for under the applicable prospectively determined payment rate;

(d) take into consideration the need to adjust payments under the system to take into account factors such as a disproportionate share of low-income patients, differences in wages and wage-related costs among facilities located in various geographic areas, and other factors the Secretary considers appropriate; and

(e) take into consideration the appropriateness of classifying patients and payments upon functional disability, cognitive impairment, and other patient characteristics.

(2) REPORTS.—(A) By not later than April 1, 1991, the Secretary (acting through the Administrator of the Health Care Financing Administration) shall submit any research studies to be used in developing the proposal under paragraph (1) to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives.

(B) By not later than September 1, 1991, the Secretary shall submit the proposal developed under paragraph (1) to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives.

(C) By not later than March 1, 1992, the Prospective Payment Assessment Commission shall submit an analysis of and comments on the proposal developed under paragraph (1) to the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives."

Use of More Recent Data Regarding Routine Service Costs of Skilled Nursing Facilities

Pub. L. 101-239, title VI, § 6024, Dec. 19, 1989, 103 Stat. 2167, as amended by Pub. L. 101-508, title IV, § 4008(e)(1), Nov. 5, 1990, 104 Stat. 1388-45, provided that: "The Secretary of Health and Human Services shall determine mean per diem routine service costs for freestanding and hospital based skilled nursing facilities under section 1888(a) of the Social Security Act [subsec. (a) of this section] for cost reporting periods beginning on or after October 1, 1989, in accordance with regulations published by the Secretary that require the use of cost reports submitted by skilled nursing facilities for cost reporting periods beginning not earlier than October 1, 1985. The Secretary shall update such costs under such section for cost reporting periods beginning on or after October 1, 1989, by using cost reports submitted by skilled nursing facilities for cost reporting periods ending not earlier than January 31, 1988, and not later than December 31, 1988."

§ 1395zz. Provider education and technical assistance

(a) Coordination of education funding

The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g) of this section, including under section 1395dd of this title) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers.

(b) Enhanced education and training

(1) Additional resources

There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) such sums as may be necessary for fiscal years beginning with fiscal year 2005.

(2) Use

The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

(c) Tailoring education and training activities for small providers or suppliers

(1) In general

Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as de-
fined in paragraph (2)). Such education and training activities for small providers of services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

(2) Small provider of services or supplier

In this subsection, the term “small provider of services or supplier” means—

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(d) Internet websites; FAQs

The Secretary, and each medicare contractor as if it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet website which—

(1) provides answers in an easily accessible format to frequently asked questions, and

(2) includes other published materials of the contractor,

that relate to providers of services and suppliers under the programs under this subchapter (and subchapter XI of this chapter insofar as it relates to such programs).

(e) Encouragement of participation in education program activities

A medicare contractor may not use a record of attendance at (or failure to attend) educational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepayment review.

(f) Construction

Nothing in this section or section 1395ddd(g) of this title shall be construed as providing for disclosure by a medicare contractor—

(1) of the screens used for identifying claims that will be subject to medical review; or

(2) of information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

(g) Definitions

For purposes of this section, the term “medicare contractor” includes the following:

(1) A medicare administrative contractor with a contract under section 1395kk–1 of this title, including a fiscal intermediary with a contract under section 1395h of this title and a carrier with a contract under section 1395u of this title.

(2) An eligible entity with a contract under section 1395ddd of this title.

Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this subchapter or subchapter IX of this chapter with respect to such activities and such provider of services or supplier.


Prior Provisions


Amendments

2003—Subsecs. (b), (c). Pub. L. 108–173, § 921(d)(1), added subsec. (b) and (c).


Subsecs. (e) to (g). Pub. L. 108–173, § 921(f)(1), added subsecs. (e) to (g).

Effective Date of 2003 Amendment


Effective Date


Small Provider Technical Assistance Demonstration Program


“(1) IN GENERAL.—The Secretary [of Health and Human Services] shall establish a demonstration program (in this section referred to as the ‘demonstration program’) under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act [this chapter] (including provisions of title XI of such Act [subchapter XI of this chapter] insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

“(2) Forms of Technical Assistance.—The technical assistance described in this paragraph is—

1 So in original. Section 1395ddd does not contain a subsec. (g).
“(A) evaluation and recommendations regarding billing and related systems; and
“(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

“(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term ‘small providers of services or suppliers’ means—
“(A) a provider of services with fewer than 25 full-time-equivalent employees; or
“(B) a supplier with fewer than 10 full-time-equivalent employees.

“(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act [subsec. (g)(2) of this section], as inserted by section 921(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity’s work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

“(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

“(d) GAO EVALUATION.—Not later than 2 years after the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

“(e) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider’s or supplier’s participation in the program) to be equal to 25 percent of the cost of the technical assistance.

“(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, from amounts not otherwise appropriated in the Treasury, such sums as may be necessary to carry out this section.”

§ 1395aaa. Contract with a consensus-based entity regarding performance measurement

(a) Contract

(1) In general

For purposes of activities conducted under this chapter, the Secretary shall identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, that meets the requirements described in subsection (c). Such contract shall provide that the entity will perform the duties described in subsection (b).

(2) Timing for first contract

As soon as practicable after July 15, 2008, the Secretary shall enter into the first contract under paragraph (1).

(3) Period of contract

A contract under paragraph (1) shall be for a period of 4 years (except as may be renewed after a subsequent bidding process).

(4) Competitive procedures

Competitive procedures (as defined in section 132 of title 41) shall be used to enter into a contract under paragraph (1).

(b) Duties

The duties described in this subsection are the following:

(1) Priority setting process

The entity shall synthesize evidence and convene key stakeholders to make recommendations, with respect to activities conducted under this chapter, on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall—

(A) ensure that priority is given to measures—

(i) that address the health care provided to patients with prevalent, high-cost chronic diseases;

(ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and

(iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons; and

(B) take into account measures that—

(i) may assist consumers and patients in making informed health care decisions;

(ii) address health disparities across groups and areas; and

(iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings.

(2) Endorsement of measures

The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure—

(A) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and

(B) is consistent across types of health care providers, including hospitals and physicians.

(3) Maintenance of measures

The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.

(4) Promotion of the development of electronic health records

The entity shall promote the development and use of electronic health records that contain the functionality for automated collec-
tion, aggregation, and transmission of performance measurement information.

(5) Annual report to Congress and the Secretary; secretarial publication and comment
(A) Annual report
By not later than March 1 of each year (beginning with 2009), the entity shall submit to Congress and the Secretary a report containing a description of—
(i) the implementation of quality measurement initiatives under this chapter and the coordination of such initiatives with quality initiatives implemented by other payers;
(ii) the recommendations made under paragraph (1);
(iii) the performance by the entity of the duties required under the contract entered into with the Secretary under subsection (a);
(iv) gaps in endorsed quality measures, which shall include measures that are within priority areas identified by the Secretary under the national strategy established under section 280j of this title, and where quality measures are unavailable or inadequate to identify or address such gaps;
(v) areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under the national strategy established under section 280j of this title and where targeted research may address such gaps;
(vi) the matters described in clauses (i) and (ii) of paragraph (7)(A).
(B) Secretarial review and publication of annual report
Not later than 6 months after receiving a report under subparagraph (A) for a year, the Secretary shall—
(i) review such report; and
(ii) publish such report in the Federal Register, together with any comments of the Secretary on such report.

(6) Review and endorsement of episode group under the physician feedback program
The entity shall provide for the review and, as appropriate, the endorsement of the episode grouper developed by the Secretary under section 1395w–4(n)(9)(A) of this title. Such review shall be conducted on an expedited basis.

(7) Convening multi-stakeholder groups
(A) In general
The entity shall convene multi-stakeholder groups to provide input on—
(i) the selection of quality and efficiency measures described in subparagraph (B), from among—
(I) such measures that have been endorsed by the entity; and
(II) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and
(ii) national priorities (as identified under section 280j of this title) for improvement in population health and in the delivery of health care services for consideration under the national strategy established under section 280j of this title.
(B) Quality and efficiency measures
(i) In general
Subject to clause (ii), the quality and efficiency measures described in this subparagraph are quality and efficiency measures—
(I) for use pursuant to sections 1395f(i)(5)(D), 1395f(i)(7), 1395f(t)(17), 1395w–4(k)(2)(C), 1395cc(k)(3), 1395rr(b)(2)(A)(iii), 1395ww(b)(3)(B)(viii), 1395ww(j)(7)(D), 1395ww(m)(5)(D), 1395ww(o)(2), 1395wws(s)(4)(D), and 1395ff(b)(3)(B)(v) of this title;
(II) for use in reporting performance information to the public; and
(iii) for use in health care programs other than for use under this chapter.
(ii) Exclusion
Data sets (such as the outcome and assessment information set for home health services and the minimum data set for skilled nursing facility services) that are used for purposes of classification systems used in establishing payment rates under this subchapter shall not be quality and efficiency measures described in this subparagraph.

(C) Requirement for transparency in process
(i) In general
In convening multi-stakeholder groups under subparagraph (A) with respect to the selection of quality and efficiency measures, the entity shall provide for an open and transparent process for the activities conducted pursuant to such convening.
(ii) Selection of organizations participating in multi-stakeholder groups
The process described in clause (i) shall ensure that the selection of representatives comprising such groups provides for public nominations for, and the opportunity for public comment on, such selection.

(D) Multi-stakeholder group defined
In this paragraph, the term "multi-stakeholder group" means, with respect to a quality and efficiency measure, a voluntary collaborative of organizations representing a broad group of stakeholders interested in or affected by the use of such quality and efficiency measure.

(8) Transmission of multi-stakeholder input
Not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups provided under paragraph (7).

(c) Requirements described
The requirements described in this subsection are the following:

(1) Private nonprofit
The entity is a private nonprofit entity governed by a board.
(2) **Board membership**

The members of the board of the entity include—

(A) representatives of health plans and health care providers and practitioners or representatives of groups representing such health plans and health care providers and practitioners;

(B) health care consumers or representatives of groups representing health care consumers; and

(C) representatives of purchasers and employers or representatives of groups representing purchasers or employers.

(3) **Entity membership**

The membership of the entity includes persons who have experience with—

(A) urban health care issues;

(B) safety net health care issues;

(C) rural and frontier health care issues; and

(D) health care quality and safety issues.

(4) **Open and transparent**

With respect to matters related to the contract with the Secretary under subsection (a), the entity conducts its business in an open and transparent manner and provides the opportunity for public comment on its activities.

(5) **Voluntary consensus standards setting organization**

The entity operates as a voluntary consensus standards setting organization as defined for purposes of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Public Law 104–113) and Office of Management and Budget Revised Circular A–119 (published in the Federal Register on February 10, 1998).

(6) **Experience**

The entity has at least 4 years of experience in establishing national consensus standards.

(7) **Membership fees**

If the entity requires a membership fee for participation in the functions of the entity, such fees shall be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case shall membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.

(d) **Funding**

For purposes of carrying out this section, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title (in such proportion as the Secretary determines appropriate), of $10,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2009 through 2012.

mit to the Secretary the input of multi-stakeholder groups described in paragraph (1).

(4) Consideration of multi-stakeholder input

The Secretary shall take into consideration the input from multi-stakeholder groups described in paragraph (1) in selecting quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title that have been endorsed by the entity with a contract under section 1395aaa of this title and measures that have not been endorsed by such entity.

(5) Rationale for use of quality and efficiency measures

The Secretary shall publish in the Federal Register the rationale for the use of any quality and efficiency measure described in section 1395aaa(b)(7)(B) of this title that has not been endorsed by the entity with a contract under section 1395aaa of this title.

(6) Assessment of impact

Not later than March 1, 2012, and at least once every three years thereafter, the Secretary shall—

(A) conduct an assessment of the quality and efficiency impact of the use of endorsed measures described in section 1395aaa(b)(7)(B) of this title; and

(B) make such assessment available to the public.

(b) Process for dissemination of measures used by the Secretary

(1) In general

The Secretary shall establish a process for disseminating quality and efficiency measures used by the Secretary. Such process shall include the following:

(A) The incorporation of such measures, where applicable, in workforce programs, training curricula, and any other means of dissemination determined appropriate by the Secretary.

(B) The dissemination of such quality and efficiency measures through the national strategy developed under section 280j of this title.

(2) Existing methods

To the extent practicable, the Secretary shall utilize and expand existing dissemination methods in disseminating quality and efficiency measures under the process established under paragraph (1).

(c) Review of quality and efficiency measures used by the Secretary

(1) In general

The Secretary shall—

(A) periodically (but in no case less often than once every 3 years) review quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title; and

(B) with respect to each such measure, determine whether to—

(i) maintain the use of such measure; or

(ii) phase out such measure.

(2) Considerations

In conducting the review under paragraph (1), the Secretary shall take steps to—

(A) seek to avoid duplication of measures used; and

(B) take into consideration current innovative methodologies and strategies for quality and efficiency improvement practices in the delivery of health care services that represent best practices for such quality and efficiency improvement and measures endorsed by the entity with a contract under section 1395aaa of this title since the previous review by the Secretary.

(d) Rule of construction

Nothing in this section shall preclude a State from using the quality and efficiency measures identified under sections 1320b–9a and 1320b–9b of this title.

(e) Development of quality and efficiency measures

The Administrator of the Center for Medicare & Medicaid Services shall through contracts develop quality and efficiency measures (as determined appropriate by the Administrator) for use under this chapter. In developing such measures, the Administrator shall consult with the Director of the Agency for Healthcare Research and Quality.

(f) Hospital acquired conditions

The Secretary shall, to the extent practicable, publicly report on measures for hospital-acquired conditions that are currently utilized by the Centers for Medicare & Medicaid Services for the adjustment of the amount of payment to hospitals based on rates of hospital-acquired infections.


AMENDMENTS


§ 1395bbb. Conditions of participation for home health agencies; home health quality

(a) Conditions of participation; protection of individual rights; notification of State entities; use of home health aides; medical equipment; individual's plan of care; compliance with Federal, State, and local laws and regulations

The conditions of participation that a home health agency is required to meet under this subsection are as follows:

(1) The agency protects and promotes the rights of each individual under its care, including each of the following rights:

(A) The right to be fully informed in advance of any changes in the care or treatment to be provided by the agency that may affect the individual's well-being, and (except with respect to an individual adjudged incompetent) to participate in plan-
ning care and treatment or changes in care or treatment.

(B) The right to voice grievances with respect to treatment or care that is (or fails to be) furnished without discrimination or reprisal for voicing grievances.

(C) The right to confidentiality of the clinical records described in section 1395x(o)(3) of this title.

(D) The right to have one's property treated with respect.

(E) The right to be fully informed orally and in writing (in advance of coming under the care of the agency) of—

(i) all items and services furnished by (or under arrangements with) the agency for which payment may be made under this subchapter.

(ii) the coverage available for such items and services under this subchapter, subchapter XIX of this chapter, and any other Federal program of which the agency is reasonably aware.

(iii) any changes for items and services not covered under this subchapter and any charges the individual may have to pay with respect to items and services furnished by (or under arrangements with) the agency, and

(iv) any changes in the charges or items and services described in clause (i), (ii), or (iii).

(F) The right to be fully informed in writing (in advance of coming under the care of the agency) of the individual's rights and obligations under this subchapter.

(G) The right to be informed of the availability of the State home health agency hotline established under section 1395aa(a) of this title.

(2) The agency notifies the State entity responsible for the licensing or certification of the agency of a change in—

(A) the persons with an ownership or control interest (as defined in section 1320a-9(a)(3) of this title) in the agency;

(B) the persons who are officers, directors, agents, or managing employees (as defined in section 1320a-5(b) of this title) of the agency, and

(C) the corporation, association, or other entity responsible for the management of the agency.

Such notice shall be given at the time of the change and shall include the identity of each new person or company described in the previous sentence.

(3)(A) The agency must not use as a home health aide (on a full-time, temporary, per diem, or other basis) any individual to provide items or services described in section 1395x(m) of this title on or after January 1, 1990, unless the individual—

(i) has completed a training and competency evaluation program, or a competency evaluation program, that meets the minimum standards established by the Secretary under subparagraph (D), and

(ii) is competent to provide such items and services.

For purposes of clause (i), an individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of such a program, there has been a continuous period of 24 consecutive months during none of which the individual provided items and services described in section 1395x(m) of this title for compensation.

(B)(i) The agency must provide, with respect to individuals used as a home health aide by the agency as of July 1, 1989, for a competency evaluation program (as described in subparagraph (A)(i)) and such preparation as may be necessary for the individual to complete such a program by January 1, 1990.

(ii) The agency must provide such regular performance review and regular in-service education as assures that individuals used to provide items and services described in section 1395x(m) of this title are competent to provide those items and services.

(C) The agency must not permit an individual, other than in a training and competency evaluation program that meets the minimum standards established by the Secretary under subparagraph (D), to provide items or services of a type for which the individual has not demonstrated competency.

(D)(i) The Secretary shall establish minimum standards for the programs described in subparagraph (A) by not later than October 1, 1988.

(ii) Such standards shall include the content of the curriculum, minimum hours of training, qualification of instructors, and procedures for determination of competency.

(iii) Such standards may permit approval of programs offered by or in home health agencies, as well as outside agencies (including employee organizations), and of programs in effect on December 22, 1987: except that they may not provide for the approval of a program offered by or in a home health agency which, within the previous 2 years—

(I) has been determined to be out of compliance with subparagraph (A), (B), or (C);

(II) has been subject to an extended (or partial extended) survey under subsection (c)(2)(D) of this section;

(III) has been assessed a civil money penalty described in subsection (f)(2)(A)(I) of this section of not less than $5,000; or

(IV) has been subject to the remedies described in subsection (e)(1) of this section or in clauses (ii) or (iii) of subsection (f)(2)(A) of this section.

(iv) Such standards shall permit a determination that an individual who has completed (before July 1, 1989) a training and competency evaluation program or a competency evaluation program shall be deemed for purposes of subparagraph (A) to have completed a program that is approved by the Secretary under the standards established under this subparagraph if the Secretary determines that, at the time the program was offered, the program met such standards.

(E) In this paragraph, the term "home health aide" means any individual who pro-
vides the items and services described in section 1395x(m) of this title, but does not include an individual—

(i) who is a licensed health professional (as defined in subparagraph (F)), or

(ii) who volunteers to provide such services without monetary compensation.

(F) In this paragraph, the term "licensed health professional" means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, physical or occupational therapy assistant, registered professional nurse, licensed practical nurse, or licensed or certified social worker.

The requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.

(b) Duty of Secretary

It is the duty and responsibility of the Secretary to assure that the conditions of participation and requirements specified in or pursuant to section 1395x(o) of this title and subsection (a) of this section and the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency and to promote the effective and efficient use of public moneys.

(c) Surveys of home health agencies

(1) Any agreement entered into or renewed by the Secretary pursuant to section 1395aa of this title relating to home health agencies shall provide that the appropriate State or local agency shall conduct, without any prior notice, a standard survey of each home health agency. Any individual who notifies (or causes to be notified) a home health agency of the time or date on which such a survey is scheduled to be conducted is subject to a civil money penalty of not to exceed $2,000. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a of this title. The Secretary shall review each State's or local agency's procedures for scheduling and conduct of standard surveys to assure that the State or agency has taken all reasonable steps to avoid giving notice of such a survey through the scheduling procedures and the conduct of the surveys themselves.

(2)(A) Except as provided in subparagraph (B), each home health agency shall be subject to a standard survey not later than 36 months after the date of the previous standard survey conducted under this paragraph. The Secretary shall establish a frequency for surveys of home health agencies within this 36-month interval commensurate with the need to assure the delivery of quality home health services.

(B) If not otherwise conducted under subparagraph (A), a standard survey (or an abbreviated standard survey) of an agency—

(i) may be conducted within 2 months of any change of ownership, administration, or management of the agency to determine whether the change has resulted in any decline in the quality of care furnished by the agency, and

(ii) shall be conducted within 2 months of when a significant number of complaints have been reported with respect to the agency to the Secretary, the State, the entity responsible for the licensing of the agency, the State or local agency responsible for maintaining a toll-free hotline and investigative unit (under section 1395aa(a) of this title), or any other appropriate Federal, State, or local agency.

(C) A standard survey conducted under this paragraph with respect to a home health agency—

(i) shall include (to the extent practicable), for a case-mix stratified sample of individuals furnished items or services by the agency—

(I) visits to the homes of such individuals, but only with the consent of such individuals, for the purpose of evaluating (in accordance with a standardized, reproducible assessment instrument (or instruments) approved by the Secretary under subsection (d) of this section) the extent to which the quality and scope of items and services furnished by the agency attained and maintained the highest practicable functional capacity of each such individual as reflected in such individual's written plan of care required under section 1395x(m) of this title and clinical records required under section 1395x(o)(3) of this title; and

(II) a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care;

(ii) shall be based upon a protocol that is developed, tested, and validated by the Secretary not later than January 1, 1989; and

(iii) shall be conducted by an individual—

(I) who meets minimum qualifications established by the Secretary not later than July 1, 1989,

(II) who is not serving (or has not served within the previous 2 years) as a member of the staff of, or as a consultant to, the home health agency surveyed respecting compliance with the conditions of participation specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section, and

(III) who has no personal or familial financial interest in the home health agency surveyed.

(D) Each home health agency that is found, under a standard survey, to have provided substandard care shall be subject to an extended survey to review and identify the policies and procedures which produced such substandard
care and to determine whether the agency has complied with the conditions of participation specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section. Any other agency may, at the Secretary’s or State’s discretion, be subject to subsection (f) of this section, in lieu of terminating the certification of the agency. If, after such a period of intermediate sanctions, the agency is still no longer in compliance with the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section, the Secretary shall terminate the certification of the agency.

(d) Assessment process; reports to Congress

(1) Not later than January 1, 1989, the Secretary shall designate an assessment instrument (or instrument) for use by an agency in complying with subsection (c)(2)(C)(i)(I) of this section.

(2)(A) Not later than January 1, 1992, the Secretary shall—
(i) evaluate the assessment process,
(ii) report to Congress on the results of such evaluation, and
(iii) based on such evaluation, make such modifications in the assessment process as the Secretary determines are appropriate.

(B) The Secretary shall periodically update the evaluation conducted under subparagraph (A), report the results of such update to Congress, and, based on such update, make such modifications in the assessment process as the Secretary determines are appropriate.

(c) Enforcement

(1) If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this subchapter is no longer in compliance with the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section and determines that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subsection (f)(2)(A)(i) of this section or terminate the certification of the agency, and may provide, in addition, for 1 or more of the other remedies described in subsection (f)(2)(A) of this section.

(2) If the Secretary determines on the basis of a standard, extended, or partial extended survey or otherwise, that a home health agency that is certified for participation under this subchapter is no longer in compliance with the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section and determines that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the agency furnishes items and services, the Secretary may (for a period not to exceed 6 months) impose intermediate sanctions developed pursuant to subsection (f) of this section, and, in lieu of terminating the certification of the agency. If, after such a period of intermediate sanctions, the agency is still no longer in compliance with the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section, the Secretary shall terminate the certification of the agency.

(f) Intermediate sanctions

(1) The Secretary shall develop and implement, by not later than April 1, 1989—
(A) a range of intermediate sanctions to apply to home health agencies under the conditions described in subsection (e) of this section, and
(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

(2)(A) The intermediate sanctions developed under paragraph (1) shall include—
(i) civil money penalties in an amount not to exceed $10,000 for each day of noncompliance,
(ii) suspension of all or part of the payments to which a home health agency would otherwise be entitled under this subchapter with respect to items and services furnished by a home health agency on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (e)(2) of this section, and
(iii) the appointment of temporary management to oversee the operation of the home health agency and to protect and assure the health and safety of the individuals under the care of the agency while improvements are made in order to bring the agency into compliance with all the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section.

The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title. The temporary management under clause (iii) shall not be terminated until the Secretary has determined that the agency has the management capability to ensure continued compliance with all the requirements referred to in that clause.

(B) The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and shall not be construed as limiting other remedies, including any remedy available to an individual at common law.

(C) A finding to suspend payment under paragraph (A) shall terminate when the Secretary finds that the home health agency is in substantial compliance with all the requirements specified in or pursuant to section 1395x(o) of this title and subsection (a) of this section.

(3) The Secretary shall develop and implement, by not later than April 1, 1989, specific procedures with respect to the conditions under which each of the intermediate sanctions developed under paragraph (1) is to be applied, including the amount of any fines and the severity of each of these sanctions. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these sanctions and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

(g) Payment on basis of location of service

A home health agency shall submit claims for payment for home health services under this subsection only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.


Subsect. (a)(3)(A). Pub. L. 100–360, §411(d)(1)(A)(i), amended third sentence as read follows: "The Secretary shall provide for imposition of civil money penalties under this clause in a manner similar to that for the imposition of civil money penalties under section 1395a-7a of this title." Subsect. (a)(3)(B). Pub. L. 100–360, §411(d)(1)(A)(ii), redesignated pars. (5) and (6) as (4) and (5), respectively, and struck out former par. (4) which read as follows: "With respect to durable medical equipment furnished to individuals for whom the agency provides items and services, suppliers of such equipment do not use (on a full-time, temporary, per diem, or other basis) any individual who does not meet minimum training standards (established by the Secretary by October 1, 1988) for the demonstration and use of such equipment furnished to individuals with respect to whom payments may be made under this subchapter." Subsect. (a)(3)(C). Pub. L. 100–360, §411(d)(1)(A)(iii), inserted "physical or occupational therapy assistant," after "occupational therapist".

Subsect. (a)(4) to (6). Pub. L. 100–360, §411(d)(1)(A)(iii), redesignated pars. (5) and (6) as (5) and (6), respectively, and struck out former par. (4) which read as follows: "With respect to durable medical equipment furnished to individuals for whom the agency provides items and services, suppliers of such equipment do not use (on a full-time, temporary, per diem, or other basis) any individual who does not meet minimum training standards (established by the Secretary by October 1, 1988) for the demonstration and use of such equipment furnished to individuals with respect to whom payments may be made under this subchapter." Subsect. (c)(1). Pub. L. 100–360, §411(d)(2)(A), as amended by Pub. L. 100–485, §608(d)(20)(A), amended third sentence as read follows: "The Secretary shall provide for imposition of civil money penalties under this clause in a manner similar to that for the imposition of civil money penalties under section 1395a-7a of this title." Subsect. (d)(2)(A). Pub. L. 100–360, §411(d)(2)(B), substituted "1992" for "1991" in introductory provisions.


Subsec. (f)(2)(A). Pub. L. 100–360, §411(d)(3)(B)(iii), inserted before last sentence: "The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title." Pub. L. 100–360, §411(d)(3)(B)(ii), realigned the margins of cl. (i) to (iii) and concluding provisions.

Subsect. (f)(2)(A)(i). Pub. L. 100–360, §411(d)(3)(B)(ii), substituted "in an amount not to exceed $10,000 for each day of noncompliance" for "for each day of noncompliance".

1967—Subsecs. (c), (d). Pub. L. 100–203, §4022(a), added subsec. (c) and (d).

Subsec. (e). Pub. L. 100–203, §4023(a), as amended by Pub. L. 100–360, §411(d)(3)(B)(ii), substituted "in an amount not to exceed $10,000 for each day of noncompliance" for "for each day of noncompliance".

1997—Subsec. (g). Pub. L. 105–33 substituted "physical or occupational therapy assistant," for "occupational therapist".

Effective Date of 1997 Amendment

Amendment by Pub. L. 105–33 applicable to cost reporting periods beginning on or after Oct. 1, 1997, see section 6604(c) of Pub. L. 105–33, set out as a note under section 1395a of this title.

Effective Date of 1990 Amendment

Amendment by section 4206(h)(2) of Pub. L. 101–508 applicable with respect to services furnished on or after the first day of the first month beginning more than 1 year after Nov. 5, 1990, see section 4206(e)(1) of Pub. L.
101–508, set out as a note under section 1395i–3 of this title.


Section 4207(i)(2), formerly 4027(i)(2), of Pub. L. 101–508, as renumbered and amended by Pub. L. 103–432, title I, §160(d)(4), (11), Oct. 31, 1994, 108 Stat. 4444, provided that: "The amendments made by paragraph (ii) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203], except that the Secretary may not permit approval of a training and competency evaluation program or a competency evaluation program offered by or in a home health agency which, pursuant to any Federal or State law within the Act period beginning on October 1, 1986—

"(i) had its participation terminated under title XVIII of the Social Security Act [this subchapter];

"(ii) was assessed a civil money penalty not less than $5,000 for deficiencies in applicable quality standards for home health agencies;

"(iii) was subject to suspension by the Secretary of all or part of the payments to which it would otherwise be entitled under such title;

"(iv) operated under a temporary management appointed to oversee the operation of the agency and to ensure the health and safety of the agency's patients; or

"(v) pursuant to State action, was closed or had its patients transferred."

**Effective Date of 1988 Amendments**

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 608g(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

**Effective Date of 1987 Amendment**

Section 4022(b) of Pub. L. 100–203 provided that: "Except as otherwise specifically provided in section 1891(d) of the Social Security Act [subsec. (d) of this section] (as added by subsection (a)), the amendment made by subsection (a) [amending this section] shall become effective on the first day of the 18th calendar month to begin after the date of the enactment of this Act [Dec. 22, 1987]."

Section 4023(b) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(d)(3)(C), July 1, 1988, 102 Stat. 774, provided that: "Except as otherwise specifically provided in subsections (e) and (f) of section 1891 of the Social Security Act [subsecs. (e) and (f) of this section] (as added by subsection (a)), the amendment made by subsection (a) [amending this section] shall become effective on the first day of the 18th calendar month to begin after the date of the enactment of this Act [Dec. 22, 1987], and no intermediate sanction described in section 1891(c)(2)(A) of such Act [subsec. (c)(2)(A) of this section] shall be imposed for violations occurring before such effective date."

**Effective Date**

Section applicable to home health agencies as of the first day of the 18th calendar month that begins after Dec. 22, 1987, except as otherwise provided, see section 4023(c) of Pub. L. 100–203, set out as an Effective Date of 1987 Amendment note under section 1396x of this title.

**TREATMENT OF BRANCH OFFICES; GAO STUDY ON SUPERVISION OF HOME HEALTH CARE PROVIDED IN ISOLATED RURAL AREAS**

Pub. L. 100–554, §10(a)(6) [title V, §506], Dec. 21, 2000, 114 Stat. 2763, 2763A–351, provided that:

"(a) TREATMENT OF BRANCH OFFICES.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, in determining for purposes of title XVIII of the Social Security Act [this subchapter] whether an office of a home health agency constitutes a branch office or a separate home health agency, neither the time nor distance between a parent office of the home health agency and a branch office shall be the sole determinant of a home health agency's branch office status.

"(2) CONSIDERATION OF FORMS OF TECHNOLOGY IN DEFINITION OF SUPERVISION.—The Secretary of Health and Human Services may include forms of technology in determining what constitutes 'supervision' for purposes of determining a home health agency's branch office status under paragraph (1).

"(b) GAO STUDY.—

"(1) STUDY.—The Comptroller General of the United States shall conduct a study of the provision of adequate supervision to maintain quality of home health services delivered under the medicare program under title XVIII of the Social Security Act [this subchapter] in isolated rural areas. The study shall evaluate the methods that home health agencies and subunits use to maintain adequate supervision in the delivery of services to clients residing in those areas, how these methods of supervision compare to requirements that subunits independently meet medicare conditions of participation, and the resources utilized by subunits to meet such conditions.

"(2) REPORT.—Not later than January 1, 2002, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). The report shall include recommendations on whether exceptions are needed for subunits and branches of home health agencies under the medicare program to maintain access to the home health benefit or whether alternative policies should be developed to assure adequate supervision and access and recommendations on whether a national standard for supervision is appropriate."

§1395ecc. Offset of payments to individuals to collect past-due obligations arising from breach of scholarship and loan contract

(a) In general

(1)(A) Subject to subparagraph (B), the Secretary shall enter into an agreement under this section with any individual who, by reason of a breach of a contract entered into by such individual pursuant to the National Health Service Corps Scholarship Program, the Physician Shortage Area Scholarship Program, or the Health Education Assistance Loan Program, owes a past-due obligation to the United States (as defined in subsection (b) of this section).

(B) The Secretary shall not enter into an agreement with an individual under this section to the extent—

(i) the individual has entered into a contract with the Secretary pursuant to section 204(a)(1) of the Public Health Service Amendments of 1987, and

(ii) the individual has fulfilled or (as determined by the Secretary) is fulfilling the terms of such contract; or

(iii) the liability of the individual under such section 204(a)(1) has otherwise been relieved under such section; or
(iii) the individual is performing such physician’s1 service obligation under a forbearance agreement entered into with the Secretary under subpart II of part D of title III of the Public Health Service Act [42 U.S.C. 254d et seq.].

(2) The agreement under this section shall provide that—

(A) deductions shall be made from the amounts otherwise payable to the individual under this subchapter, in accordance with a formula and schedule agreed to by the Secretary and the individual, until such past-due obligation (and accrued interest) have been repaid;

(B) payment under this subchapter for services provided by such individual shall be made only on an assignment-related basis;

(C) if the individual does not provide services, for which payment would otherwise be made under this subchapter, of a sufficient quantity to maintain the offset collection according to the agreed upon formula and schedule—

(i) the Secretary shall immediately inform the Attorney General, and the Attorney General shall immediately commence an action to recover the full amount of the past-due obligation, and

(ii) subject to paragraph (4), the Secretary shall immediately exclude the individual from the program under this subchapter, until such time as the entire past-due obligation has been repaid.

(3) If the individual refuses to enter into an agreement or breaches any provision of the agreement—

(A) the Secretary shall immediately inform the Attorney General, and the Attorney General shall immediately commence an action to recover the full amount of the past-due obligation, and

(B) subject to paragraph (4), the Secretary shall immediately exclude the individual from the program under this subchapter, until such time as the entire past-due obligation has been repaid.

(4) The Secretary shall not exclude an individual pursuant to paragraph (2)(C)(i) or paragraph (3)(B) if such individual is a sole community practitioner or sole source of essential specialized services in a community if a State requests that the individual not be excluded.

(b) Past-due obligation

For purposes of this section, a past-due obligation is any amount—

(1) owed by an individual to the United States by reason of a breach of a scholarship contract under section 338E of the Public Health Service Act [42 U.S.C. 254o] or under subpart III of part F of title VII of such Act (as in effect before October 1, 1976) and which has not been paid by the deadline established by the Secretary pursuant to such respective section, and has not been canceled, waived, or suspended by the Secretary pursuant to such section; or

(2) owed by an individual to the United States by reason of a loan covered by Federal loan insurance under subpart I of part C of title VII of the Public Health Service Act and payment for which has not been cancelled, waived, or suspended by the Secretary under such subpart.

(c) Collection under this section shall not be exclusive

This section shall not preclude the United States from applying other provisions of law otherwise applicable to the collection of obligations owed to the United States, including (but not limited to) the use of tax refund offsets pursuant to section 3726A of title 31 and the application of other procedures provided under chapter 37 of title 31.

(d) Collection from providers and health maintenance organizations

(1) In the case of an individual who owes a past-due obligation, and who is an employee of, or affiliated by a medical services agreement with, a provider having an agreement under section 1395cc of this title or a health maintenance organization or competitive medical plan having a contract under section 1395l of this title or section 1395mm of this title, the Secretary shall deduct the amounts of such past-due obligation from amounts otherwise payable under this subchapter to such provider, organization, or plan.

(2) Deductions shall be in accordance with a formula and schedule agreed to by the Secretary, the individual and the provider, organization, or plan. The deductions shall be made from the amounts otherwise payable to the individual under this subchapter as long as the individual continues to be employed or affiliated by a medical services agreement.

(3) Such deduction shall not be made until 6 months after the Secretary notifies the provider, organization, or plan of the amount to be deducted and the particular physicians2 to whom the deductions are attributable.

(4) A deduction made under this subsection shall relieve the individual of the obligation (to the extent of the amount collected) to the United States, but the provider, organization, or plan shall have a right of action to collect from such individual the amount deducted pursuant to this subsection (including accumulated interest).

(5) No deduction shall be made under this subsection if, within the 6-month period after notice is given to the provider, organization, or plan, the individual pays the past-due obligation, or ceases to be employed by the provider, organization, or plan.

(6) The Secretary shall also apply the provisions of this subsection in the case of an individual who is a member of a group practice, if such group practice submits bills under this program as a group, rather than by individual physicians3.

(e) Transfer from trust funds

Amounts equal to the amounts deducted pursuant to this section shall be transferred from

1So in original. Probably should be “individual’s”.

2See References in Text note below.

3So in original. Probably should be “individuals”.
the Trust Fund from which the payment to the individual, provider, or other entity would otherwise have been made, to the general fund in the Treasury, and shall be credited as payment of the past-due obligation of the individual from whom (or with respect to whom) the deduction was made. (Aug. 14, 1935, ch. 501, title XVIII, §1892, as added Pub. L. 100–203, title IV, §4052(a), Dec. 22, 1987, 101 Stat. 1330–95; amended Pub. L. 100–360, title IV, §411(f)(10)(A),(C)(i), July 1, 1988, 102 Stat. 780; Pub. L. 100–485, title VI, §608(d)(21)(E)–(H), Oct. 13, 1988, 102 Stat. 2420.)

REFERENCES IN TEXT


The Public Health Service Act, referred to in subsections (a)(1)(B)(iii) and (b), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended. Subpart III of part F of chapter 6A of this title and Tables.

Subpart II of part D of title III of the Public Health Service Act (as in effect before October 1, 1976) was classified to part I (§292 et seq.) of part A of subchapter V of chapter 6A of this title.

The Public Health Service Act (as in effect before October 1, 1976) was classified generally to subpart I (§294 et seq.) of part C of subchapter V of chapter 6A of this title.

The Public Health Service Act (as in effect before October 1, 1976) was classified generally to subpart III (§295c–21 et seq.) of part F of subchapter V of chapter 6A of this title, prior to repeal by Pub. L. 94–484, title I, §102, Oct. 12, 1976, 90 Stat. 1290. For complete classification of this Act to the Code, see Short Title note set out under section 228 of this title. There is hereby established the Medicare Integrity Program.

The Medicare Integrity Program (in this section referred to as the “Program”) under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities, or otherwise, to carry out the activities described in subsection (b) of this section.

(a) Establishment of Program

There is hereby established the Medicare Integrity Program

(b) Activities described

The activities described in this subsection are as follows:
(1) Review of activities of providers of services or other individuals and entities furnishing items and services for which payment may be made under this subchapter (including skilled nursing facilities and home health agencies), including medical and utilization review and fraud review (employing similar standards, processes, and technologies used by private health plans, including equipment and software technologies which surpass the capability of the equipment and technologies used in the review of claims under this subchapter as of August 21, 1996).

(2) Audit of cost reports.

(3) Determinations as to whether payment should not be, or should not have been, made under this subchapter by reason of section 1395y(b) of this title, and recovery of payments that should not have been made.

(4) Education of providers of services, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues.

(5) Developing (and periodically updating) a list of items of durable medical equipment in accordance with section 1395m(a)(15) of this title which are subject to prior authorization under such section.

(6) The Medicare-Medicaid Data Match Program in accordance with subsection (g).

(c) Eligibility of entities

An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) of this section if—

(1) the entity has demonstrated capability to carry out such activities;

(2) in carrying out such activities, the entity agrees to cooperate with the Inspector General of the Department of Health and Human Services, the Attorney General, and other law enforcement agencies, as appropriate, in the investigation and deterrence of fraud and abuse in relation to this subchapter and in other cases arising out of such activities;

(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

(4) the entity agrees to provide the Secretary and the Inspector General of the Department of Health and Human Services with such performance statistics (including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities by the entity) as the Secretary or the Inspector General may request; and

(5) the entity meets such other requirements as the Secretary may impose.

In the case of the activity described in subsection (b) of this section, an entity shall be deemed to be eligible to enter into a contract under the Program to carry out the activity if the entity is a carrier with a contract in effect under section 1395u of this title.

(d) Process for entering into contracts

The Secretary shall enter into contracts under the Program in accordance with such procedures as the Secretary shall by regulation establish, except that such procedures shall include the following:

(1) Procedures for identifying, evaluating, and resolving organizational conflicts of interest that are generally applicable to Federal acquisition and procurement.

(2) Competitive procedures to be used—

(A) when entering into new contracts under this section;

(B) when entering into contracts that may result in the elimination of responsibilities of an individual fiscal intermediary or carrier under section 202(b) of the Health Insurance Portability and Accountability Act of 1996; and

(C) at any other time considered appropriate by the Secretary,

except that the Secretary may continue to contract with entities that are carrying out the activities described in this section pursuant to agreements under section 1395h of this title or contracts under section 1395u of this title in effect on August 21, 1996.

(3) Procedures under which a contract under this section may be renewed without regard to any provision of law requiring competition if the contractor has met or exceeded the performance requirements established in the current contract.

The Secretary may enter into such contracts without regard to final rules having been promulgated.

(e) Limitation on contractor liability

The Secretary shall by regulation provide for the limitation of a contractor’s liability for actions taken to carry out a contract under the Program, and such regulation shall, to the extent the Secretary finds appropriate, employ the same or comparable standards and other substantive and procedural provisions as are contained in section 1320c–6 of this title.

(f) Recovery of overpayments

(1) Use of repayment plans

(A) In general

If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this subchapter would constitute a hardship (as described in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary), the Secretary shall enter into a plan with the provider of services or supplier for the repayment of such overpayment.

(B) Hardship

(i) In general

For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if—
(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this subchapter to the provider of services for the cost reporting period covered by the most recently submitted cost report; or

(ii) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this subchapter to the provider of services or supplier for the previous calendar year.

(ii) Rule of application

The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this subchapter during the previous year or was paid under this subchapter only during a portion of that year.

(iii) Treatment of previous overpayments

If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(C) Exceptions

Subparagraph (A) shall not apply if—

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this subchapter; or

(ii) there is an indication of fraud or abuse committed against the program.

(D) Immediate collection if violation of repayment plan

If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

(E) Relation to no fault provision

Nothing in this paragraph shall be construed as affecting the application of section 1395gg(c) of this title (relating to no adjustment in the cases of certain overpayments).

(2) Limitation on recoupment

(A) In general

In the case of a provider of services or supplier that is determined to have received an overpayment under this subchapter and that seeks a reconsideration by a qualified independent contractor on such determination under section 1395f(b)(1) of this title, the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1395f(b)(1) of this title (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redetermination by the fiscal intermediary or carrier involved.

(B) Collection with interest

Insofar as the determination on such appeal is against the provider of services or supplier, interest on the overpayment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) Medicare contractor defined

For purposes of this subsection, the term "medicare contractor": has the meaning given such term in section 1395gg of this title.

(3) Limitation on use of extrapolation

A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless the Secretary determines that—

(A) there is a sustained or high level of payment error; or

(B) documented educational intervention has failed to correct the payment error.

There shall be no administrative or judicial review under section 1395f of this title, section 1395oo of this title, or otherwise, of determinations by the Secretary of sustained or high levels of payment errors under this paragraph.

(4) Provision of supporting documentation

In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) Consent settlement reforms

(A) In general

The Secretary may use a consent settlement (as defined in subparagraph (D)) to settle a projected overpayment.

(B) Opportunity to submit additional information before consent settlement offer

Before offering a provider of services or supplier a consent settlement, the Secretary shall—

(i) communicate to the provider of services or supplier—

(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

(II) the nature of the problems identified in such evaluation; and
(III) the steps that the provider of services or supplier should take to address the problems; and

(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

(C) Consent settlement offer

The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the Secretary—

(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such determination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier—

(I) the opportunity for a statistically valid random sample; or

(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal rights with respect to the alleged overpayment involved.

(D) Consent settlement defined

For purposes of this paragraph, the term “consent settlement” means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

(6) Notice of over-utilization of codes

The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this subchapter (or particular billing codes may be overutilized by suppliers served by the contractor in cases in which there still appears to be an overpayment).

(B) Reporting requirements

The Secretary shall make available in a timely manner any data and statistical information collected by the Medi-Medi Program to the Attorney General, the Director of the Office of Inspector General of the Department of Health and Human Services, and the Director of the Office of Inspector General of the Department of Health and Human Services.

(g) Medicare-Medicaid Data Match Program

(1) Expansion of Program

(A) In general

The Secretary shall enter into contracts with eligible entities for the purpose of ensuring that, beginning with 2006, the Medicare-Medicaid Data Match Program (commonly referred to as the “Medi-Medi Program”) is conducted with respect to the program established under this subchapter and State Medicaid programs under subchapter XIX for the purpose of—

(i) identifying program vulnerabilities in the program established under this subchapter and the Medicaid program established under subchapter XIX through the use of computer algorithms to look for payment anomalies (including billing or billing patterns identified with respect to service, time, or patient that appear to be suspect or otherwise implausible); and

(ii) working with States, the Attorney General, and the Inspector General of the Department of Health and Human Services to coordinate appropriate actions to protect the Federal and State share of expenditures under the Medicaid program under subchapter XIX, as well as the program established under this subchapter; and

(iii) increasing the effectiveness and efficiency of both such programs through cost avoidance, savings, and recoupments of fraudulent, wasteful, or abusive expenditures.

(B) Reporting requirements

The Secretary shall make available in a timely manner any data and statistical information collected by the Medi-Medi Program to the Attorney General, the Director
of the Federal Bureau of Investigation, the Inspector General of the Department of Health and Human Services, and the States (including a Medicaid fraud and abuse control unit described in section 1396b(q) of this title). Such information shall be disseminated no less frequently than quarterly.

(2) Limited waiver authority

The Secretary shall waive only such requirements of this section and of subchapters XI and XIX as are necessary to carry out paragraph (1).

(h) Use of recovery audit contractors

(1) In general

Under the Program, the Secretary shall enter into contracts with recovery audit contractors in accordance with this subsection for the purpose of identifying underpayments and overpayments and recouping overpayments under this subchapter with respect to all services for which payment is made under this subchapter. Under the contracts—

(A) payment shall be made to such a contractor only from amounts recovered;
(B) from such amounts recovered, payment—

(i) shall be made on a contingent basis for collecting overpayments; and
(ii) may be made in such amounts as the Secretary may specify for identifying underpayments; and

(C) the Secretary shall retain a portion of the amounts recovered which shall be available to the program management account of the Centers for Medicare & Medicaid Services for purposes of activities conducted under the recovery audit program under this subsection.

(2) Disposition of remaining recoveries

The amounts recovered under such contracts that are not paid to the contractor under paragraph (1)(C) shall be applied to reduce expenditures under this subchapter.

(3) Nationwide coverage

The Secretary shall enter into contracts under paragraph (1) in a manner so as to provide for activities in all States under such a contract by not later than January 1, 2010 (not later than December 31, 2010, in the case of contractors relating to payments made under part C or D).

(4) Audit and recovery periods

Each such contract shall provide that audit and recovery activities may be conducted during a fiscal year with respect to payments made under this subchapter—

(A) during such fiscal year; and
(B) retrospectively (for a period of not more than 4 fiscal years prior to such fiscal year).

(5) Waiver

The Secretary shall waive such provisions of this subchapter as may be necessary to provide for payment of recovery audit contractors under this subsection in accordance with paragraph (1).

(6) Qualifications of contractors

(A) In general

The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor unless the contractor has staff that has the appropriate clinical knowledge of, and experience with, the payment rules and regulations under this subchapter or the contractor has, or will contract with, another entity that has such knowledgeable and experienced staff.

(B) Ineligibility of certain contractors

The Secretary may not enter into a contract under paragraph (1) with a recovery audit contractor to the extent the contractor is a fiscal intermediary under section 1395h of this title, a carrier under section 1395u of this title, or a Medicare administrative contractor under section 1395kk-1 of this title.

(C) Preference for entities with demonstrated proficiency

In awarding contracts to recovery audit contractors under paragraph (1), the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency for cost control or recovery audits with private insurers, health care providers, health plans, under the Medicaid program under subchapter XIX, or under this subchapter.

(7) Construction relating to conduct of investigation of fraud

A recovery of an overpayment to an individual or entity by a recovery audit contractor under this subsection shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpayment.

(8) Annual report

The Secretary shall annually submit to Congress a report on the use of recovery audit contractors under this subsection. Each such report shall include information on the performance of such contractors in identifying underpayments and overpayments and recouping overpayments, including an evaluation of the comparative performance of such contractors and savings to the program under this subchapter.

(9) Special rules relating to parts C and D

The Secretary shall enter into contracts under paragraph (1) to require recovery audit contractors to—

(A) ensure that each MA plan under part C has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;
(B) ensure that each prescription drug plan under part D has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan; and
(C) examine claims for reinsurance payments under section 1395w-115(b) of this title to determine whether prescription drug
plans submitting such claims incurred costs in excess of the allowable reinsurancel costs permitted under paragraph (2) of that section; and

(D) review estimates submitted by prescription drug plans by private plans with respect to the enrollment of high cost beneficiaries (as defined by the Secretary) and to compare such estimates with the numbers of such beneficiaries actually enrolled by such plans.

(i) Evaluations and annual report

(1) Evaluations

The Secretary shall conduct evaluations of eligible entities which the Secretary contracts with under the Program not less frequently than every 3 years.

(2) Annual report

Not later than 180 days after the end of each fiscal year (beginning with fiscal year 2011), the Secretary shall submit a report to Congress which identifies—

(A) the use of funds, including funds transferred from the Federal Hospital Insurance Trust Fund under section 1395h of this title and the Federal Supplementary Insurance Trust Fund under section 1395g of this title, to carry out this section; and

(B) the effectiveness of the use of such funds.


REPEALS

Sec. 5501. Repeal of section 1395eee of this title.

REFERENCES IN TEXT

Section 202(b) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (d)(2)(B), is section 202(b) of Pub. L. 104–191, which is amended by sections 1395h and 1395g of this title.

Parts C and D, referred to in subsec. (h)(3), (9), are classified to sections 1395w–21 et seq. and 1395w–101 et seq., respectively, of this title.

AMENDMENTS


Subsec. (c)(4), (5). Pub. L. 111–148, §6402(j)(1)(A), added par. (4) and redesignated former par. (4) as (5).


Subsec. (h)(2). Pub. L. 111–148, §6411(b)(2), substituted “this subchapter” for “parts A and B”.


EFFECTIVE DATE OF 2003 AMENDMENT


“(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act [subsec. (f)(1) of this section], as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act [Dec. 8, 2003].

“(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act [subsec. (f)(2) of this section], as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

“(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act [subsec. (f)(3) of this section], as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

“(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act [subsec. (f)(4) of this section], as added by subsection (a), shall take effect on the date of the enactment of this Act.

“(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act [subsec. (f)(5) of this section], as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

“(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) [1893(f)(6)] of the Social Security Act [probably means subsec. (f)(6) of this section], as added by subsection (a).

“(7) PAYMENT AUDITS.—Section 1893A(f)(7) [1893(f)(7)] of the Social Security Act [probably means subsec. (f)(7) of this section], as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

“(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893A(f)(8) [1893(f)(8)] of the Social Security Act [subsec. (f)(8) of this section], as added by subsection (a).”

ACCESS TO COORDINATION OF BENEFITS CONTRACTOR DATABASE

Pub. L. 109–432, div. B, title III, §302(b), Dec. 20, 2006, 120 Stat. 2992, provided that: “The Secretary of Health and Human Services shall provide for access by recovery audit contractors conducting audit and recovery activities under section 1893(b) of the Social Security Act [subsec. (h) of this section], as added by subsection (a), to the database of the Coordination of Benefits Contractor of the Centers for Medicare & Medicaid Services with respect to the audit and recovery periods described in paragraph (4) of such section 1893(b).”

§1395eee. Payments to, and coverage of benefits under, programs of all-inclusive care for elderly (PACE)

(a) Receipt of benefits through enrollment in PACE program; definitions for PACE program related terms

(1) Benefits through enrollment in a PACE program

In accordance with this section, in the case of an individual who is entitled to benefits under part A of this subchapter or enrolled
under part B of this subchapter and who is a PACE program eligible individual (as defined in paragraph (5)) with respect to a PACE program offered by a PACE provider under a PACE program agreement—

(A) the individual may enroll in the program under this section; and

(B) so long as the individual is so enrolled and in accordance with regulations—

(1) the individual shall receive benefits under this subchapter solely through such program; and

(2) the PACE provider is entitled to payment under and in accordance with this section and such agreement for provision of such benefits.

(2) “PACE program” defined

For purposes of this section, the term “PACE program” means a program of all-inclusive care for the elderly that meets the following requirements:

(A) Operation

The entity operating the program is a PACE provider (as defined in paragraph (3)).

(B) Comprehensive benefits

The program provides comprehensive health care services to PACE program eligible individuals in accordance with the PACE program agreement and regulations under this section.

(C) Transition

In the case of an individual who is enrolled under the program under this section and whose enrollment ceases for any reason (including that the individual no longer qualifies as a PACE program eligible individual, the termination of a PACE program agreement, or otherwise), the program provides assistance to the individual in obtaining necessary transitional care through appropriate referrals and making the individual’s medical records available to new providers.

(3) “PACE provider” defined

(A) In general

For purposes of this section, the term “PACE provider” means an entity that—

(i) subject to subparagraph (B), is (or is a distinct part of) a public entity or a private, nonprofit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986; and

(ii) has entered into a PACE program agreement with respect to its operation of a PACE program.

(B) Treatment of private, for-profit providers

Clause (i) of subparagraph (A) shall not apply—

(i) to entities subject to a demonstration project waiver under subsection (h) of this section; and

(ii) after the date the report under section 4804(b) of the Balanced Budget Act of 1997 is submitted, unless the Secretary determines that any of the findings described in subparagraph (A), (B), (C), or (D) of paragraph (2) of such section are true.

(4) “PACE program agreement” defined

For purposes of this section, the term “PACE program agreement” means, with respect to a PACE provider, an agreement, consistent with this section, section 1396u-4 of this title (if applicable), and regulations promulgated to carry out such sections, between the PACE provider and the Secretary, or an agreement between the PACE provider and a State administering agency for the operation of a PACE program by the provider under such sections.

(5) “PACE program eligible individual” defined

For purposes of this section, the term “PACE program eligible individual” means, with respect to a PACE program, an individual who—

(A) is 55 years of age or older;

(B) subject to subsection (c)(4) of this section, is determined under subsection (c) of this section to require the level of care required under the State medicaid plan for coverage of nursing facility services;

(C) resides in the service area of the PACE program; and

(D) meets such other eligibility conditions as may be imposed under the PACE program agreement for the program under subsection (e)(2)(A)(ii) of this section.

(6) “PACE protocol” defined

For purposes of this section, the term “PACE protocol” means the Protocol for the Program of All-inclusive Care for the Elderly (PACE), as published by On Lok, Inc., as of April 14, 1995, or any successor protocol that may be agreed upon between the Secretary and On Lok, Inc.

(7) “PACE demonstration waiver program” defined

For purposes of this section, the term “PACE demonstration waiver program” means a demonstration program under either of the following sections (as in effect before the date of their repeal):

(A) Section 603(c) of the Social Security Amendments of 1983 (Public Law 98–21), as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99–272).

(B) Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 (Public Law 99–509).

(8) “State administering agency” defined

For purposes of this section, the term “State administering agency” means, with respect to the operation of a PACE program in a State, the agency of that State (which may be the single agency responsible for administration of the State plan under subchapter XIX of this chapter in the State) responsible for administering PACE program agreements under this section and section 1396u-4 of this title in the State.

(9) “Trial period” defined

(A) In general

For purposes of this section, the term “trial period” means, with respect to a PACE program operated by a PACE provider under a PACE program agreement, the first 3 contract years under such agreement with respect to such program.
(B) Treatment of entities previously operating PACE demonstration waiver programs

Each contract year (including a year occurring before the effective date of this section) during which an entity has operated a PACE demonstration waiver program shall be counted under subparagraph (A) as a contract year during which the entity operated a PACE program as a PACE provider under a PACE program agreement.

(10) “Regulations” defined

For purposes of this section, the term “regulations” refers to interim final or final regulations promulgated under subsection (f) of this section to carry out this section and section 1396d-4 of this title.

(b) Scope of benefits; beneficiary safeguards

(1) In general

Under a PACE program agreement, a PACE provider shall—

(A) provide to PACE program eligible individuals enrolled with the provider, regardless of source of payment and directly or under contracts with other entities, at a minimum—

(i) all items and services covered under this subchapter (for individuals enrolled under this section) and all items and services covered under subchapter XIX of this chapter, but without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost-sharing that would otherwise apply under this subchapter or such subchapter, respectively; and

(ii) all additional items and services specified in regulations, based upon those required under the PACE protocol;

(B) provide such enrollees access to necessary covered items and services 24 hours per day, every day of the year;

(C) provide services to such enrollees through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services pursuant to regulations; and

(D) specify the covered items and services that will not be provided directly by the entity, and to arrange for delivery of those items and services through contracts meeting the requirements of regulations.

(2) Quality assurance; patient safeguards

The PACE program agreement shall require the PACE provider to have in effect at a minimum—

(A) a written plan of quality assurance and improvement, and procedures implementing such plan, in accordance with regulations; and

(B) written safeguards of the rights of enrolled participants (including a patient bill of rights and procedures for grievances and appeals) in accordance with regulations and with other requirements of this subchapter and Federal and State law that are designed for the protection of patients.

(3) Treatment of medicare services furnished by noncontract physicians and other entities

(A) Application of medicare advantage requirement with respect to medicare services furnished by noncontract physicians and other entities

Section 1395w–22(k)(1) of this title (relating to limitations on balance billing against MA organizations for noncontract physicians and other entities with respect to services covered under this subchapter) shall apply to PACE providers, PACE program eligible individuals enrolled with such PACE providers, and physicians and other entities that do not have a contract or other agreement establishing payment amounts for services furnished to such an individual in the same manner as such section applies to MA organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

(B) Reference to related provision for non-contract providers of services

For the provision relating to limitations on balance billing against PACE providers for services covered under this subchapter furnished by noncontract providers of services, see section 1395cc(a)(1)(O) of this title.

(4) Reference to related provision for services covered under subchapter XIX but not under this subchapter

For provisions relating to limitations on payments to providers participating under the State plan under subchapter XIX of this chapter, but without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost-sharing that would otherwise apply under this subchapter or such subchapter, respectively; and

(c) Eligibility determinations

(1) In general

The determination of whether an individual is a PACE program eligible individual is a PACE program eligible individual—

(A) shall be made under and in accordance with the PACE program agreement; and

(B) who is entitled to medical assistance under subchapter XIX of this chapter, shall be made (or who is not so entitled, may be made) by the State administering agency.

(2) Condition

An individual is not a PACE program eligible individual (with respect to payment under this section) unless the individual’s health status has been determined by the Secretary or the State administering agency, in accordance with regulations, to be comparable to the health status of individuals who have participated in the PACE demonstration waiver programs. Such determination shall be based upon information on health status and related indicators (such as medical diagnoses and measures of activities of daily living, instrumental activities of daily living, and cognitive impairment) that are part of a uniform mini-
(3) Annual eligibility recertifications

(A) In general
Subject to subparagraph (B), the determination described in subsection (a)(5)(B) of this section for an individual shall be reevaluated at least annually.

(B) Exception
The requirement of annual reevaluation under subparagraph (A) may be waived during a period in accordance with regulations in those cases where the State administering agency determines that there is no reasonable expectation of improvement or significant change in an individual’s condition during the period because of the severity of chronic condition, or degree of impairment of functional capacity of the individual involved.

(4) Continuation of eligibility
An individual who is a PACE program eligible individual may be deemed to continue to be such an individual notwithstanding a determination that the individual no longer meets the requirements of that section if, in accordance with regulations, the absence of continued coverage under a PACE program the individual reasonably would be expected to meet such requirements within the succeeding 6-month period.

(5) Enrollment; disenrollment

(A) Voluntary disenrollment at any time
The enrollment and disenrollment of PACE program eligible individuals in a PACE program shall be pursuant to regulations and the PACE program agreement and shall permit enrollees to voluntarily disenroll without cause at any time.

(B) Limitations on disenrollment

(i) In general
Regulations promulgated by the Secretary under this section and section 1396u–4 of this title, and the PACE program agreement, shall provide that the PACE program may not disenroll a PACE program eligible individual except—

(I) for nonpayment of premiums (if applicable) on a timely basis; or

(II) for engaging in disruptive or threatening behavior, as defined in such regulations (developed in close consultation with State administering agencies).

(ii) No disenrollment for noncompliant behavior
Except as allowed under regulations promulgated to carry out clause (i)(II), a PACE program may not disenroll a PACE program eligible individual on the ground that the individual has engaged in noncompliant behavior if such behavior is related to a mental or physical condition of the individual. For purposes of the preceding sentence, the term “noncompliant behavior” includes repeated noncompliance with medical advice and repeated failure to appear for appointments.

(iii) Timely review of proposed nonvoluntary disenrollment
A proposed disenrollment, other than a voluntary disenrollment, shall be subject to timely review and final determination by the Secretary or by the State administering agency (as applicable), prior to the proposed disenrollment becoming effective.

(d) Payments to PACE providers on capitated basis

(1) In general
In the case of a PACE program agreement under this section, except as provided in this subsection or by regulations, the Secretary shall make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled under the agreement under this section in the same manner and from the same sources as payments are made to a Medicare+ Choice organization under section 1395w–23 of this title (or, for periods beginning before January 1, 1999, to an eligible organization under a risk-sharing contract under section 1395mm of this title). Such payments shall be subject to adjustment in the manner described in section 1395w–23(a)(2) of this title or section 1395mm(a)(1)(E) of this title, as the case may be.

(2) Capitation amount
The capitation amount to be applied under this subsection for a provider for a contract year shall be an amount specified in the PACE program agreement for the year. Such amount shall be based upon payment rates established for purposes of payment under section 1395w–23 of this title (or, for periods before January 1, 1999, for purposes of risk-sharing contracts under section 1395mm of this title) and shall be adjusted to take into account the comparative frailty of PACE enrollees and such other factors as the Secretary determines to be appropriate. Such amount under such an agreement shall be computed in a manner so that the total payment level for all PACE program eligible individuals enrolled under a program is less than the projected payment under this subchapter for a comparable population not enrolled under a PACE program.

(3) Capitation rates determined without regard to the phase-out of the indirect costs of medical education from the annual Medicare Advantage capitation rate
Capitation amounts under this subsection shall be determined without regard to the application of section 1395w–23(k)(4) of this title.

(e) PACE program agreement

(1) Requirement

(A) In general
The Secretary, in close cooperation with the State administering agency, shall establish procedures for entering into, extending, and terminating PACE program agreements for the operation of PACE programs by entities that meet the requirements for a PACE provider under this section, section 1396u–4 of this title, and regulations.
(B) Numerical limitation

(i) In general

The Secretary shall not permit the number of PACE providers with which agreements are in effect under this section or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 to exceed—

(I) 40 as of August 5, 1997; or

(II) as of each succeeding anniversary of August 5, 1997, the numerical limitation under this subparagraph for the preceding year plus 20.

Subclause (II) shall apply without regard to the actual number of agreements in effect as of a previous anniversary date.

(ii) Treatment of certain private, for-profit providers

The numerical limitation in clause (i) shall not apply to a PACE provider that—

(I) is operating under a demonstration project waiver under subsection (h) of this section; or

(II) was operating under such a waiver and subsequently qualifies for PACE provider status pursuant to subsection (a)(3)(B)(ii) of this section.

(2) Service area and eligibility

(A) In general

A PACE program agreement for a PACE program—

(i) shall designate the service area of the program;

(ii) may provide additional requirements for individuals to qualify as PACE program eligible individuals with respect to the program;

(iii) shall be effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate and is subject to termination by the Secretary and the State administering agency at any time for cause (as provided under the agreement);

(iv) shall require a PACE provider to meet all applicable State and local laws and requirements; and

(v) shall contain such additional terms and conditions as the parties may agree to, so long as such terms and conditions are consistent with this section and regulations.

(B) Service area overlap

In designating a service area under a PACE program agreement under subparagraph (A)(i), the Secretary (in consultation with the State administering agency) may exclude from designation an area that is already covered under another PACE program agreement, in order to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

(3) Data collection; development of outcome measures

(A) Data collection

(i) In general

Under a PACE program agreement, the PACE provider shall—

(N) collect data;

(II) maintain, and afford the Secretary and the State administering agency access to, the records relating to the program, including pertinent financial, medical, and personnel records; and

(III) make available to the Secretary and the State administering agency reports that the Secretary finds (in consultation with State administering agencies) necessary to monitor the operation, cost, and effectiveness of the PACE program under this section and section 1396u–4 of this title.

(ii) Requirements during trial period

During the first 3 years of operation of a PACE program (either under this section or under a PACE demonstration waiver program), the PACE provider shall provide such additional data as the Secretary specifies in regulations in order to perform the oversight required under paragraph (4)(A).

(B) Development of outcome measures

Under a PACE program agreement, the PACE provider, the Secretary, and the State administering agency shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE program eligible individuals.

(4) Oversight

(A) Annual, close oversight during trial period

During the trial period (as defined in subsection (a)(9) of this section) with respect to a PACE program operated by a PACE provider, the Secretary (in cooperation with the State administering agency) shall conduct a comprehensive annual review of the operation of the PACE program by the provider in order to assure compliance with the requirements of this section and regulations. Such a review shall include—

(i) an on-site visit to the program site;

(ii) comprehensive assessment of a provider’s fiscal soundness;

(iii) comprehensive assessment of the provider’s capacity to provide all PACE services to all enrolled participants;

(iv) detailed analysis of the entity’s substantial compliance with all significant requirements of this section and regulations; and

(v) any other elements the Secretary or State administering agency considers necessary or appropriate.

(B) Continuing oversight

After the trial period, the Secretary (in cooperation with the State administering agency) shall continue to conduct such review of the operation of PACE providers and PACE programs as may be appropriate, taking into account the performance level of a provider and compliance of a provider with all significant requirements of this section and regulations.

(C) Disclosure

The results of reviews under this paragraph shall be reported promptly to the
PACE provider, along with any recommendations for changes to the provider's program, and shall be made available to the public upon request.

(5) Termination of PACE provider agreements

(A) In general

Under regulations—

(i) the Secretary or a State administering agency may terminate a PACE program agreement for cause; and

(ii) a PACE provider may terminate an agreement after appropriate notice to the Secretary, the State agency, and enrollees.

(B) Causes for termination

In accordance with regulations establishing procedures for termination of PACE program agreements, the Secretary or a State administering agency may terminate a PACE program agreement with a PACE provider for, among other reasons, the fact that—

(i) the Secretary or State administering agency determines that—

(I) there are significant deficiencies in the quality of care provided to enrolled participants; or

(II) the provider has failed to comply substantially with conditions for a program or provider under this section or section 1396u–4 of this title; and

(ii) the entity has failed to develop and successfully initiate, within 30 days of the date of the receipt of written notice of such a determination, a plan to correct the deficiencies, or has failed to continue implementation of such a plan.

(C) Termination and transition procedures

An entity whose PACE provider agreement is terminated under this paragraph shall implement the transition procedures required under subsection (a)(2)(C) of this section.

(6) Secretary's oversight; enforcement authority

(A) In general

Under regulations, if the Secretary determines (after consultation with the State administering agency) that a PACE provider is failing substantially to comply with the requirements of this section and regulations, the Secretary (and the State administering agency) may take any or all of the following actions:

(i) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(ii) Withhold some or all further payments under the PACE program agreement under this section or section 1396u–4 of this title with respect to PACE program services furnished by such provider until the deficiencies have been corrected.

(iii) Terminate such agreement.

(B) Application of intermediate sanctions

Under regulations, the Secretary may provide for the application against a PACE provider of remedies described in section 1395w–27(g)(2) (or, for periods before January 1, 1999, section 1395mm(i)(6)(B) of this title) or 1396b(m)(5)(B) of this title in the case of violations by the provider of the type described in section 1395w–27(g)(1) (or section 1395mm(i)(6)(A) of this title for such periods) or 1396b(m)(5)(A) of this title, respectively (in relation to agreements, enrollees, and requirements under this section or section 1396u–4 of this title, respectively).

(7) Procedures for termination or imposition of sanctions

Under regulations, the provisions of section 1395w–27(h) of this title (or for periods before January 1, 1999, section 1395mm(i)(9) of this title) shall apply to termination and sanctions respecting a PACE program agreement and PACE provider under this subsection in the same manner as they apply to a termination and sanctions with respect to a contract and a Medicare+Choice organization under part C of this subchapter (or for such periods an eligible organization under section 1395mm of this title).

(8) Timely consideration of applications for PACE program provider status

In considering an application for PACE provider program status, the application shall be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information that is needed in order to make a final determination with respect to the application. After the date the Secretary receives such additional information, the application shall be deemed approved unless the Secretary, within 90 days of such date, denies such request.

(f) Regulations

(1) In general

The Secretary shall issue interim final or final regulations to carry out this section and section 1396u–4 of this title.

(2) Use of PACE protocol

(A) In general

In issuing such regulations, the Secretary shall, to the extent consistent with the provisions of this section, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.

(B) Flexibility

In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use nonstaff physicians according to State licensing law requirements) under this section and section 1396u–4 of this title, the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions:
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(i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
(ii) The delivery of comprehensive, integrated acute and long-term care services.
(iii) The interdisciplinary team approach to care management and service delivery.
(iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.
(v) The assumption by the provider of full financial risk.

(C) Application of certain additional beneficiary and program protections

(A) In general

In issuing such regulations and subject to subparagraph (B), the Secretary may apply with respect to PACE programs, providers, and agreements such requirements of part C of this subchapter (or, for periods before January 1, 1999, section 1395mm of this title) and sections 1396b(m) and 1396u–2 of this title relating to protection of beneficiaries and program integrity as would apply to Medicare+Choice organizations under part C of this subchapter (or for such periods eligible organizations under risk-sharing contracts under section 1390mm of this title) and to Medicaid managed care organizations under prepaid capitation agreements under section 1396b(m) of this title.

(B) Considerations

In issuing such regulations, the Secretary shall—

(i) take into account the differences between populations served and benefits provided under this section and under part C of this subchapter (or, for periods before January 1, 1999, section 1395mm of this title) and section 1396b(m) of this title;
(ii) not include any requirement that conflicts with carrying out PACE programs under this section; and
(iii) not include any requirement restricting the proportion of enrollees who are eligible for benefits under this subchapter or subchapter XIX of this chapter.

(4) Construction

Nothing in this subsection shall be construed as preventing the Secretary from including in regulations provisions to ensure the health and safety of individuals enrolled in a PACE program under this section that are in addition to those otherwise provided under paragraphs (2) and (3).

(g) Waivers of requirements

With respect to carrying out a PACE program under this section, the following requirements of this subchapter (and regulations relating to such requirements) are waived and shall not apply:

(1) Section 1395d of this title, insofar as it limits coverage of institutional services.
(2) Sections 1395e, 1395f, 1395l, and 1395sw of this title, insofar as such sections relate to rules for payment for benefits.
(3) Sections 1395f(a)(2)(B), 1395f(a)(2)(C), and 1395n(a)(2)(A) of this title, insofar as they limit coverage of extended care services or home health services.
(4) Section 1395x(i) of this title, insofar as it imposes a 3-day prior hospitalization requirement for coverage of extended care services.
(5) Paragraphs (1) and (9) of section 1395y(a) of this title, insofar as they may prevent payment for PACE program services to individuals enrolled under PACE programs.

(h) Demonstration project for for-profit entities

(1) In general

In order to demonstrate the operation of a PACE program by a private, for-profit entity, the Secretary (in close consultation with State administering agencies) shall grant waivers from the requirement under subsection (a)(3) of this section that a PACE provider may not be a for-profit, private entity.

(2) Similar terms and conditions

(A) In general

Except as provided under subparagraph (B), and paragraph (1), the terms and conditions for operation of a PACE program by a provider under this subsection shall be the same as those for PACE providers that are nonprofit, private organizations.

(B) Numerical limitation

The number of programs for which waivers are granted under this subsection shall not exceed 10. Programs with waivers granted under this subsection shall not be counted against the numerical limitation specified in subsection (e)(1)(B) of this section.

(i) Miscellaneous provisions

Nothing in this section or section 1396u–4 of this title shall be construed as preventing a PACE provider from entering into contracts with other governmental or nongovernmental payers for the care of PACE program eligible individuals who are not eligible for benefits under part A of this subchapter, or enrolled under part B of this subchapter, or eligible for medical assistance under subchapter XIX of this title.

Section 9220 of Pub. L. 99–272, title IX, Apr. 20, 1983, referred to in subsec. (a)(7)(A), is section 603(c) of Pub. L. 98–21, title VI, Apr. 20, 1983, which was not classified to the Code and was repealed by Pub. L. 105–33, which is set out as a note below.


For the effective date of this section, referred to in subsec. (a)(9)(B), see section 4803 of Pub. L. 105–33, set out below.

AMENDMENTS

2010—Subsecs. (h) to (j). Pub. L. 111–148, § 3201(i)(1), which directed addition of subsec. (h) and the redesignation of former subsec. (h) and (i) as (i) and (j), respectively, was repealed by Pub. L. 111–152, title I, § 1102(a).

Prior to repeal, text of subsec. (h) read as follows:

"With respect to a PACE program under this section, the following provisions (and regulations relating to such provisions) shall not apply:

"(1) Section 1395w–23(h)(1)(A)(i) of this title, relating to MA area-specific non-drug monthly benchmark amount being based on competitive bids.

"(2) Section 1395w–23(d)(5) of this title, relating to the establishment of MA local plan service areas.

"(3) Section 1395w–23(n) of this title, relating to the payment of performance bonuses.

"(4) Section 1395w–23(o) of this title, relating to grandfathering supplemental benefits for current enrollees after implementation of competitive bidding.

"(5) Section 1395w–23(p) of this title, relating to transitional extra benefits."

See Effective Date of 2010 Amendment note below.


CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Repeal of section 3230 of Pub. L. 111–148 and the amendments made by such section, effective as if included in the enactment of Pub. L. 111–148, see section 1102(a) of Pub. L. 111–152, set out as a note under section 1395w–21 of this title.
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“(c) Any other efforts determined by the rural PACE pilot site to be critical to its successful startup, as approved by the Secretary.

“(d) Appropriation.—

“(1) In general.—Out of funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $10,000,000 to carry out this subsection for fiscal year 2006.

“(2) Availability.—Funds appropriated under clause (1) shall remain available for expenditure through fiscal year 2006.

“(3) Technical assistance program.—The Secretary shall establish a technical assistance program to provide—

(A) outreach and education to State agencies and provider organizations interested in establishing PACE programs in rural areas; and

(B) technical assistance necessary to support rural PACE pilot sites.

“(4) Outlier protection for rural PACE pilot sites.—

“(1) Establishment of fund for reimbursement of outlier costs.—Notwithstanding any other provision of law, the Secretary shall establish an outlier fund to reimburse rural PACE pilot sites for recognized outlier costs (as defined in paragraph (5)) incurred for eligible outlier participants (as defined in paragraph (3)) in an amount, subject to paragraph (4), equal to 80 percent of the amount by which the recognized outlier costs exceed $50,000.

“(2) Eligible outlier participant.—For purposes of this subsection, the term ‘eligible outlier participant’ means a PACE program eligible individual (as defined in sections 1894(a)(5) and 1934(a)(5) of the Social Security Act (42 U.S.C. 1395eee(a)(5); 1396u–4(a)(5))) who resides in a rural area and with respect to whom the rural PACE pilot site incurs more than $50,000 in recognized costs in a 12-month period.

“(3) Recognized outlier costs defined.—

“(A) In general.—For purposes of this subsection, the term ‘recognized outlier costs’ means, with respect to services furnished to an eligible outlier participant by a rural PACE pilot site, the least of the following (as documented by the site to the Secretary for the provision of inpatient and attendant services for the eligible outlier participant in a given 12-month period):

(i) If the services are provided under a contract, the total amount of outlier expense payments made under the contract; and the provider, the payment rate specified under the contract.

(ii) The payment rate established under the original Medicare fee-for-service program for such service.

(iii) The amount actually paid for the services by the pilot site.

“(B) Inclusion in only one period.—Recognized outlier costs may not be included in more than one 12-month period.

“(C) Limitation of outlier cost reimbursement period.—A rural PACE pilot site shall only receive outlier expense payments under this subsection with respect to costs incurred during the first 3 years of the site’s operation.

“(5) Requirement to access risk reserves prior to payment.—A rural PACE pilot site shall access and exhaust any risk reserves held or arranged for the provider (other than revenue or reserves maintained to satisfy the requirements of section 660.80(c) of title 42, Code of Federal Regulations) and any working capital established through a site development grant awarded under subsection (b)(1), prior to receiving any payment from the outlier fund.

“(6) Application.—In order to receive an outlier expense payment under this subsection with respect to an eligible outlier participant, a rural PACE pilot site shall submit an application containing—

(A) documentation of the costs incurred with respect to the participant.

(B) a certification that the site has complied with the requirements under paragraph (4); and

(C) such additional information as the Secretary may require.

“(7) Appropriation.—

“(A) In general.—Out of funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $10,000,000 to carry out this subsection for the period of fiscal years 2006 through 2010.

“(B) Availability.—Funds appropriated under subparagraph (A) shall remain available for obligation through fiscal year 2010.

“(8) Evaluation of PACE Providers Serving Rural Service Areas.—Not later than 60 months after the date of enactment of this Act (Feb. 8, 2006), the Secretary shall submit a report to Congress containing an evaluation of the experience of rural PACE pilot sites.

“(e) Amounts in addition to payments under Social Security Act.—Any amounts paid under the authority of this section to a PACE provider shall be in addition to payments made to the provider under section 1894 or 1934 of the Social Security Act (42 U.S.C. 1395eee; 1396a–4)."

FLEXIBILITY IN EXERCISING WAIVER AUTHORITY


(1) shall approve or deny a request for a modification or a waiver of provisions of the PACE protocol not later than 90 days after the date the Secretary receives the request; and

(2) may exercise authority to modify or waive such provisions in a manner that responds promptly to the needs of PACE programs relating to areas of employment and the use of community-based primary care physicians.”

TRANSITION; REGULATIONS

Section 4803 of title IV of Pub. L. 105–33, as amended by Pub. L. 106–554, § 1(a)(6) [title IX, § 901], Dec. 21, 2000, 114 Stat. 2763, 2763A–582, provided that:

“(a) Timely issuance of regulations; effective date.—The Secretary of Health and Human Services shall promulgate regulations to carry out this subtitle [title I (§§ 4801–4809) of title IV of Pub. L. 105–33, enacting this section and section 1396u–4 of this title, amending sections 1396b, 1386d, 1386r–5, and 1396v of this title, and enacting provisions set out as notes under this section and section 1396b–6 of this title] in a timely manner. Such regulations shall be designed so that entities may establish and operate PACE programs under sections 1894 and 1934 of the Social Security Act (this section and section 1396u–4 of this title) (as added by sections 4801 and 4802 of this subtitle) for periods beginning not later than 1 year after the date of the enactment of this Act [Aug. 5, 1997].
“(b) EXPANSION AND TRANSITION FOR PACE DEMONSTRATION PROJECT WAIVERS.—

“(1) EXPANSION IN CURRENT NUMBER AND EXTENSION OF DEMONSTRATION PROJECTS.—Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 [see subsec. (d) below], as amended by section 1118(g) of the Omnibus Budget Reconciliation Act of 1987, is amended—

“(A) in paragraph (1), by inserting before the period at the end the following: ‘, except that the Secretary shall grant waivers of such requirements to up to the applicable numerical limitation specified in sections 1894(e)(1)(B) and 1935(e)(1)(B) of the Social Security Act’ [subsection (e)(1)(B) of this section and section 1396u–4(e)(1)(B) of this title]; and

“(B) in paragraph (2)—

“(i) in subparagraph (A), by striking ‘, including permitting the organization to assume progressively (over the initial 3-year period of the waiver) the full financial risk’; and

“(ii) in subparagraph (C), by adding at the end the following: ‘In granting further extensions, an organization shall not be required to provide for reporting of information which is only required because of the demonstration nature of the project.’

“(2) ELIMINATION OF REPLICATION REQUIREMENT.—Section 9412(b)(2)(B) of such Act, as so amended, shall not apply to waivers granted under such section after the date of the enactment of this Act [Aug. 5, 1997].

“(3) TIMELY CONSIDERATION OF APPLICATIONS.—In considering an application for waivers under such section before the effective date of the repeals under subsection (d), subject to the numerical limitation under the amendment made by paragraph (1), the application shall be deemed approved unless the Secretary of Health and Human Services, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information which is needed in order to make a final determination with respect to the application. After the date the Secretary receives such additional information, the application shall be deemed approved unless the Secretary, within 90 days of such date, denies such request.

“(c) PRIORITY AND SPECIAL CONSIDERATION IN APPLICATION.—During the 3-year period beginning on the date of the enactment of this Act [Aug. 5, 1997]:

“(1) PROVIDER STATUS.—The Secretary of Health and Human Services shall give priority in processing applications of entities to qualify as PACE programs under section 1894 or 1934 of the Social Security Act (the section and section 1396u–4 of this title)—

“(A) first, to entities that are operating a PACE demonstration waiver program (as defined in sections 1894(a)(7) and 1934(a)(8) of the Social Security Act [subsection and section 1396u–4 of this title]); and

“(B) then to entities that have applied to operate such a program as of May 1, 1997.

“(2) NEW WAIVERS.—The Secretary shall give priority in the awarding of additional waivers under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 [see subsection (d) below]—

“(A) to any entities that have applied for such waivers under such section as of May 1, 1997; and

“(B) to any entity that, as of May 1, 1997, has formally contracted with a State to provide services for which payment is made on a capitated basis with an understanding that the entity was seeking to become a PACE provider.

“(d) REPEAL OF CURRENT PACE DEMONSTRATION PROJECT WAIVER AUTHORITY.—

“(1) IN GENERAL.—Subject to paragraph (2), the following provisions of law are repealed:

“(A) Section 603(c) of the Social Security Amendments of 1979 (Public Law 96–21) [97 Stat. 118].

“(B) Section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Public Law 99–272) [100 Stat. 183].

“(C) Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 (Public Law 99–509) [100 Stat. 2662].

“(2) DELAY IN APPLICATION TO CURRENT WAIVERS.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case of waivers granted with respect to a PACE program before July 1, 2000, the repeals made by paragraph (1) shall not apply until the end of a transition period (of up to 36 months) that begins on the initial effective date of such regulations, and that allows sufficient time for an orderly transition from demonstration project authority to general authority provided under the revised section.

“(B) STATE OPTION TO SEEK EXTENSION OF CURRENT PERIOD.—A State may elect to maintain the PACE programs which (as of the date of the enactment of this Act [Aug. 5, 1997]) were operating in the State under the authority described in paragraph (1) until a date (specified by the State) that is not later than 4 years after the initial effective date of regulations described in subsection (a). If a State makes such an election, the repeals made by paragraph (1) shall not apply to the programs until the date so specified, but only so long as such programs continue to operate under the same terms and conditions as apply to such programs as of the date of the enactment of this Act, and subparagraph (A) shall not apply to such programs.”

PACE PROGRAMS: STUDY AND REPORTS

Section 4801(a), (b) of title IV of Pub. L. 105–33, enacting this section and section 1396u–4 of this title and amending sections 1396b, 1396d, 1396k–5, and 1396v of this title.

“(2) DELAY IN APPLICATION TO CURRENT WAIVERS.—

“(A) IN GENERAL.—Subject to subparagraph (B), in the case of waivers granted with respect to a PACE program before July 1, 2000, the repeals made by paragraph (1) shall not apply until the end of a transition period (of up to 36 months) that begins on the initial effective date of such regulations, and that allows sufficient time for an orderly transition from demonstration project authority to general authority provided under the revised section.

“(B) STATE OPTION TO SEEK EXTENSION OF CURRENT PERIOD.—A State may elect to maintain the PACE programs which (as of the date of the enactment of this Act [Aug. 5, 1997]) were operating in the State under the authority described in paragraph (1) until a date (specified by the State) that is not later than 4 years after the initial effective date of regulations described in subsection (a). If a State makes such an election, the repeals made by paragraph (1) shall not apply to the programs until the date so specified, but only so long as such programs continue to operate under the same terms and conditions as apply to such programs as of the date of the enactment of this Act, and subparagraph (A) shall not apply to such programs.”

“PACe PROGRAMS: STUDY AND REPORTS

Section 4801(a), (b) of title IV of Pub. L. 105–33 provided that:

“(a) STUDY.—

“(1) IN GENERAL.—The Secretary of Health and Human Services (in close consultation with State administering agencies, agencies as defined in sections 1894(a)(8) and 1934(a)(8) of the Social Security Act [subsection and section 1396u–4 of this title]) shall conduct a study of the quality and cost of providing PACE program services under the Medicare and Medicaid programs under the amendments made by this subtitle [subtitle I (§§4801–4804) of title IV of Pub. L. 105–33, enacting this section and section 1396u–4 of this title and amending sections 1396b, 1396d, 1396k–5, and 1396v of this title].

“(2) STUDY OF PRIVATE, FOR-PROFIT PROVIDERS.—Such study shall specifically compare the costs, quality, and access to services by entities that are private, for-profit entities operating under demonstration projects waivers granted under sections 1894(h) and 1934(h) of the Social Security Act [subsection (b) of this section and section 1396u–4(k) of this title] with the costs, quality, and access to services of other PACE providers.

“(b) REPORT.—

“(1) IN GENERAL.—Not later than 4 years after the date of the enactment of this Act [Aug. 5, 1997], the Secretary shall provide for a report to Congress on the impact of such amendments on quality and cost of services. The Secretary shall include in such report such recommendations for changes in the operation of such amendments as the Secretary deems appropriate.

“(2) TREATMENT OF PRIVATE, FOR-PROFIT PROVIDERS.—The report shall include specific findings on whether any of the following findings is true:

“(A) The number of covered lives enrolled with entities operating under demonstration project
waivers under sections 1394(h) and 1394(h) of the Social Security Act is fewer than 800 (or such lesser number as the Secretary may find statistically sufficient to make determinations respecting findings described in the succeeding subparagraphs).

(2) The population enrolled with such entities is less frail than the population enrolled with other PACE providers.

(3) Access to or quality of care for individuals enrolled with such entities is lower than such access or quality for individuals enrolled with other PACE providers.

(4) The application of such section has resulted in an increase in expenditures under the medicare or medicaid programs above the expenditures that would have been made if such section did not apply.''

§ 1395fff. Prospective payment for home health services

(a) In general

Notwithstanding section 1395x(v) of this title, the Secretary shall provide, for portions of cost reporting periods occurring on or after October 1, 2000, for payments for home health services in accordance with a prospective payment system established by the Secretary under this section.

(b) System of prospective payment for home health services

(1) In general

The Secretary shall establish under this subsection a prospective payment system for payment for all costs of home health services. Under the system under this subsection all services covered and paid on a reasonable cost basis under the medicare home health benefit as of August 5, 1997, including medical supplies, shall be paid for on the basis of a prospective payment amount determined under this subsection and applicable to the services involved. In implementing the system, the Secretary may provide for a transition (of not longer than 4 years) during which a portion of such payment is based on agency-specific costs, but only if such transition does not result in aggregate payments under this subsection that exceed the aggregate payments that would have been made if such a transition did not occur.

(2) Unit of payment

In defining a prospective payment amount under the system under this subsection, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

(3) Payment basis

(A) Initial basis

(i) In general

Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

(I) Such amount (or amounts) shall initially be based on the most current audited cost report data available to the Secretary and shall be computed in a manner so that the total amounts payable under the system for the 12-month period beginning on the date the Secretary implements the system shall be equal to the total amount that would have been made if the system had not been in effect and if section 1395x(v)(1)(L)(ix) of this title had not been enacted.

(ii) For the 12-month period beginning after the period described in subparagraph (I), such amount (or amounts) shall be equal to the amount (or amounts) determined under subclause (I), updated under subparagraph (B).

(iii) Subject to clause (iii), for periods beginning after the period described in subparagraph (II), such amount (or amounts) shall be equal to the amount (or amounts) that would have been determined under subclause (I) that would have been made for fiscal year 2001 if the system had not been in effect and if section 1395x(v)(1)(L)(ix) of this title had not been enacted but if the reduction in limits described in clause (ii) had been in effect, updated under subparagraph (B).

Each such amount shall be standardized in a manner that eliminates the effect of variations in relative case mix and area wage adjustments among different home health agencies in a budget neutral manner consistent with the case mix and wage level adjustments provided under paragraph (4)(A). Under the system, the Secretary may recognize regional differences or differences based upon whether or not the services or agency are in an urbanized area.

(ii) Reduction

The reduction described in this clause is a reduction by 15 percent in the cost limits and per beneficiary limits described in section 1395x(v)(1)(L) of this title, as those limits are in effect on September 30, 2000.

(iii) Adjustment for 2014 and subsequent years

(I) In general

Subject to subclause (II), for 2014 and subsequent years, the amount (or amounts) that would otherwise be applicable under clause (I)(III) shall be adjusted by a percentage determined appropriate by the Secretary to reflect such factors as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other factors that the Secretary considers to be relevant. In conducting the analysis under the preceding sentence, the Secretary may consider differences between hospital-based and freestanding agencies, between for-profit and nonprofit agencies, and between the resource costs of urban and rural agencies. Such adjustment shall be made before the update
under subparagraph (B) is applied for the year.

(II) Transition

The Secretary shall provide for a 4-year phase-in (in equal increments) of the adjustment under subclause (I), with such adjustment being fully implemented for 2017. During each year of such phase-in, the amount of any adjustment under subclause (I) for the year may not exceed 3.5 percent of the amount (or amounts) applicable under clause (i)(III) as of March 23, 2010.

(B) Annual update

(i) In general

The standard prospective payment amount (or amounts) shall be adjusted for fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004) in a prospective manner specified by the Secretary by the home health applicable increase percentage (as defined in clause (ii)) applicable to the fiscal year or year involved.

(ii) Home health applicable increase percentage

For purposes of this subparagraph, the term “home health applicable increase percentage” means, with respect to—

(I) each of fiscal years 2002 and 2003, the home health market basket percentage increase (as defined in clause (iii)) minus 1.1 percentage points;

(II) for the last calendar quarter of 2003 and the first calendar quarter of 2004, the home health market basket percentage increase;

(III) the last 3 calendar quarters of 2004, and all of 2005, the home health market basket percentage increase minus 0.8 percentage points;

(IV) 2006, 0 percent; and

(V) any subsequent year, subject to clauses (v) and (vi), the home health market basket percentage increase.

(iii) Home health market basket percentage increase

For purposes of this subsection, the term “home health market basket percentage increase” means, with respect to a fiscal year or year, a percentage (estimated by the Secretary before the beginning of the fiscal year or year) determined and applied with respect to the mix of goods and services included in home health services in the same manner as the market basket percentage increase under section 1395ww(b)(3)(B)(iii) of this title; and

(iv) Adjustment for case mix changes

Insofar as the Secretary determines that the adjustments under paragraph (4)(A)(1) for a previous fiscal year or year (or estimates that such adjustments for a future fiscal year or year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year or year that is a result of changes in the coding or classification of different units of services that do not reflect real changes in case mix, the Secretary may adjust the standard prospective payment amount (or amounts) under paragraph (3) for subsequent fiscal years or years so as to eliminate the effect of such coding or classification changes.

(v) Adjustment if quality data not submitted

(I) Adjustment

For purposes of clause (ii)(V), for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subsection (B), with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points. Such reduction shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the prospective payment amount under this section for a subsequent year, and the Medicare Payment Advisory Commission shall carry out the requirements under section 5201(d) of the Deficit Reduction Act of 2005.

(II) Submission of quality data

For 2007 and each subsequent year, each home health agency shall submit to the Secretary such data that the Secretary determines are appropriate for the measurement of health care quality. Such data shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this clause.

(III) Public availability of data submitted

The Secretary shall establish procedures for making data submitted under subclause (II) available to the public. Such procedures shall ensure that a home health agency has the opportunity to review the data that is to be made public with respect to the agency prior to such data being made public.

(vi) Adjustments

After determining the home health market basket percentage increase under clause (iii), and after application of clause (v), the Secretary shall reduce such percentage—

(I) for 2015 and each subsequent year, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(II) for each of 2011, 2012, and 2013, by 1 percentage point.

The application of this clause may result in the home health market basket percent-
age increase under clause (iii) being less than 0.0 for a year, and may result in payment rates under the system under this subsection for a year being less than such payment rates for the preceding year.

(C) Adjustment for outliers

The Secretary shall reduce the standard prospective payment amount (or amounts) under this paragraph applicable to home health services furnished during a period by such proportion as will result in an aggregate reduction in payments for the period equal to 5 percent of the total payments estimated to be made based on the prospective payment system under this subsection for the period.

(4) Payment computation

(A) In general

The payment amount for a unit of home health services shall be the applicable standard prospective payment amount adjusted as follows:

(i) Case mix adjustment

The amount shall be adjusted by an appropriate case mix adjustment factor (established under subparagraph (B)).

(ii) Area wage adjustment

The portion of such amount that the Secretary estimates to be attributable to wages and wage-related costs shall be adjusted for geographic differences in such costs by an area wage adjustment factor (established under subparagraph (C)) for the area in which the services are furnished or such other area as the Secretary may specify.

(B) Establishment of case mix adjustment factors

The Secretary shall establish appropriate case mix adjustment factors for home health services in a manner that explains a significant amount of the variation in cost among different units of services.

(C) Establishment of area wage adjustment factors

The Secretary shall establish area wage adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services in a geographic area compared to the national average applicable level. Such factors may be the factors used by the Secretary for purposes of section 1395ww(d)(3)(B) of this title.

(5) Outliers

(A) In general

Subject to subparagraph (B), the Secretary may provide for an addition or adjustment to the payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. The total amount of the additional payments or payment adjustments made under this paragraph with respect to a fiscal year or year may not exceed 2.5 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection in that year.

(B) Program specific outlier cap

The estimated total amount of additional payments or payment adjustments made under subparagraph (A) with respect to a home health agency for a year (beginning with 2011) may not exceed an amount equal to 10 percent of the estimated total amount of payments made under this section (without regard to this paragraph) with respect to the home health agency for the year.

(6) Proration of prospective payment amounts

If a beneficiary elects to transfer to, or receive services from, another home health agency within the period covered by the prospective payment amount, the payment shall be prorated between the home health agencies involved.

(c) Requirements for payment information

With respect to home health services furnished on or after October 1, 1998, no claim for such a service may be paid under this subchapter unless—

(1) the claim has the unique identifier (provided under section 1395u(r) of this title) for the physician who prescribed the services or made the certification described in section 1395f(a)(2) or 1395m(a)(2)(A) of this title; and

(2) in the case of a service visit described in paragraph (1), (2), (3), or (4) of section 1395x(m) of this title, the claim contains a code (or codes) specified by the Secretary that identifies the length of time of the service visit, as measured in 15 minute increments.

(d) Limitation on review

There shall be no administrative or judicial review under section 1395f of this title, 1395oo of this title, or otherwise of—

(1) the establishment of a transition period under subsection (b)(1) of this section;

(2) the definition and application of payment units under subsection (b)(2) of this section;

(3) the computation of initial standard prospective payment amounts under subsection (b)(3)(A) of this section (including the reduction described in clause (ii) of such subsection);

(4) the establishment of the adjustment for outliers under subsection (b)(3)(C) of this section;

(5) the establishment of case mix and area wage adjustments under subsection (b)(4) of this section; and

(6) the establishment of any adjustments for outliers under subsection (b)(6) of this section.

(e) Construction related to home health services

(1) Telecommunications

Nothing in this section shall be construed as preventing a home health agency furnishing a home health unit of service for which payment is made under the prospective payment system established by this section for such units of service from furnishing services via a telecommunication system if such services—

(A) do not substitute for in-person home health services ordered as part of a plan of
care certified by a physician pursuant to section 1395f(a)(2)(C) or 1395m(a)(2)(A) of this title; and
(B) are not considered a home health visit for purposes of eligibility or payment under subchapter V of this chapter.

(2) Physician certification

Nothing in this section shall be construed as waiving the requirement for a physician certification under section 1395f(a)(2)(C) or 1395m(a)(2)(A) of this title for the payment for home health services, whether or not furnished via a telecommunications system.

References in Text

Section 5201 of the Deficit Reduction Act of 2005, referred to in subsec. (b)(3)(B)(vi), is section 5201(d) of the Deficit Reduction Act of 2005,

AMENDMENTS


Subsec. (b)(3)(B). Pub. L. 105-277, §5101(d)(2)(A), substituted “home health applicable increase percentage (as defined in clause (ii)) for “home health market basket percentage increase”.


Subsec. (b)(3)(B)(ii), (iii). Pub. L. 105-277, §5101(d)(2)(B), (C), added cl. (ii) and redesignated former cl. (ii) as (iii).

**Effective Date of 2000 Amendment**

Pub. L. 106-554, §1(a)(6) [title V, §5101(c)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–529, provided that: “The amendments made by section 321(m) [title III, §303(b)] of Pub. L. 106–113 effective as if included in the enactment as the Secretary determines appropriate.

**Effective Date of 1999 Amendment**

Amendment by section 1000(a)(6) (title III, §303(b)) of Pub. L. 106–113 applicable to services furnished by home health agencies and groups representing Medicare beneficiaries, such as—

(A) home health agencies and groups representing Medicare beneficiaries, such as—

(B) variations in service costs for providing care to individuals who are dually eligible under the Medicare and Medicaid programs;

(C) the presence of severe or chronic diseases, which might be measured by multiple, discontinuous home health episodes;

(D) poverty status, such as evidenced by the receipt of Supplemental Security Income under title XVI of the Social Security Act [42 U.S.C. 1381 et seq.]; and

(E) other factors determined appropriate by the Secretary.

(3) REPORT.—Not later than March 1, 2014, the Secretary shall submit to Congress a report on the demonstration project under paragraph (1), together with recommendations for such legislative and administrative actions as the Secretary determines appropriate.

(4) CONSULTATIONS.—In conducting the study under paragraph (1), the Secretary shall consult with appropriate stakeholders, such as groups representing home health agencies and groups representing Medicare beneficiaries.

(5) MEDICAID DEMONSTRATION PROJECT BASED ON THE RESULTS OF THE STUDY.—

(A) IN GENERAL.—Subject to subparagraph (D), taking into account the results of the study conducted under paragraph (1), the Secretary may, as determined appropriate, provide for a demonstration project to conduct demonstrations to test whether making payment adjustments for home health services furnished during a period to offset any increase in payments during such period results in a substantial improvement in care for patients with high severity levels of illness or for low-income or underserved Medicare beneficiaries.

(B) WAIVER OF BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395f(ff)) applicable to home health services furnished during a period to offset any increase in payments during such period resulting from the application of the payment adjustments under subparagraph (A).

(C) NO EFFECT ON SUBSEQUENT PERIODS.—A payment adjustment resulting from the application of subparagraph (A) for a period—

(i) shall not apply to payments for home health services under title XVIII (42 U.S.C. 1395 et seq.) after such period; and

(ii) shall not be taken into account in calculating the payment amounts applicable for such services after such period.

(4) **Duration.**—If the Secretary determines it appropriate to conduct the demonstration project under this subsection, the Secretary shall conduct the project for a four year period beginning not later than January 1, 2015.

(4) **Funding.**—The Secretary shall provide for the demonstration project to be conducted by the Social Security Administration, pursuant to section 2003 of the Social Security Act (42 U.S.C. 1320c–11) from funds made available for this purpose under section 1807(b) of the Social Security Act (42 U.S.C. 1395f).
(F) Evaluation and report.—If the Secretary determines it appropriate to conduct the demonstration project under this subsection, the Secretary shall—

(1) provide for an evaluation of the project; and

(2) submit to Congress, by a date specified by the Secretary, a report on the project.

(G) Administration.—Chapter 36 of title 44, United States Code, shall not apply with respect to this subsection.

Temporary Increase for Home Health Services Furnished in a Rural Area


(a) In General.—With respect to episodes and visits ending on or after April 1, 2004, and before April 1, 2005, episodes and visits beginning on or after January 1, 2006, and before January 1, 2007, and episodes and visits ending on or after April 1, 2010, and before January 1, 2016, in the case of home health services furnished in a rural area (as defined in section 1861(d)) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D)), the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent in the case of episodes and visits ending on or after April 1, 2010, and before January 1, 2016, in the case of home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

(b) Waiving Budget Neutrality.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

(c) No Effect on Subsequent Periods.—The payment increase provided under subsection (a) for a period under such subsection—

(1) shall not apply to episodes and visits ending after such period; and

(2) shall not be taken into account in calculating the payment amounts applicable for episodes and visits occurring after such period.

Demonstration Project for Medical Adult Day-Care Services


(a) Establishment.—Subject to the succeeding provisions of this section, the Secretary [of Health and Human Services] shall establish a demonstration project (in this section referred to as the ‘demonstration project’) under which the Secretary shall, as part of a plan of an episode of care for home health services established for a Medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day-care facility, to provide medical adult day-care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary’s home.

(b) Payment.—

(1) In General.—Subject to paragraph (2), the amount of payment for an episode of care for medical adult day-care services, a portion of which consists of substitute medical adult day-care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 U.S.C. 1395fff). In no case may a home health agency, or a medical adult day-care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day-care services furnished under the plan of care.

(c) Adjustment in Case of Overutilization of Substitute Adult Day-Care Services to Ensure Budget Neutrality.—The Secretary shall monitor the expenditures under the demonstration project and under title XVIII of the Social Security Act [this subchapter] for home health services. If the Secretary estimates that the total expenditures under the demonstration project and under such title XVIII for home health services for a period determined by the Secretary exceed expenditures that would have been made under such title XVIII for home health services for such period if the demonstration project had not been conducted, the Secretary shall adjust the rate of payment to medical adult day-care facilities under paragraph (1) in order to eliminate such excess.

(d) Demonstration Project Sites.—The demonstration project established under this section shall be conducted in not more than 5 sites in States selected by the Secretary that license or certify providers of services that furnish medical adult day-care services.

(e) Voluntary Participation.—Participation of Medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) Preference in Selecting Agencies.—In selecting home health agencies to participate in the demonstration project, the Secretary shall give such priority to those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day-care services.

(g) Waiver Authority.—The Secretary may waive such requirements of title XVIII of the Social Security Act [this subchapter] as may be necessary for the purposes of carrying out the demonstration project. Other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) Evaluation and Report.—The Secretary shall conduct an evaluation of the clinical and cost-effectiveness of the demonstration project. Not later than 6 months after the completion of the project, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the Medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions.

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) Definitions.—In this section:

(1) Home Health Agency.—The term ‘home health agency’ has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

(2) Medical Adult Day-Care Facility.—The term ‘medical adult day-care facility’ means a facility that—

(A) has been licensed or certified by a State to furnish medical adult day-care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly under arrangement with a home health agency;

(C) is licensed and certified by the State in which it operates or meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day-care services.

(3) Medical Adult Day-Care Services.—The term ‘medical adult day-care services’ means—

(A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) [probably means section 1861(m) of the Social Security Act which is classified to section 1395x(m) of this title] furnished in a medical adult day-care facility;
"(B) a program of supervised activities furnished in a group setting in the facility that—
"(1) meet such criteria as the Secretary determines appropriate; and
"(2) is designed to promote physical and mental health of the individuals; and
"(C) such other services as the Secretary may specify.

"(4) MEDICARE BENEFICIARY.—The term ‘medicare beneficiary’ means an individual entitled to benefits under part A of this title [probably means part A of title XVIII of the Social Security Act which is classified to part A of this subchapter], enrolled under part B of this title [probably means part B of title XVIII of the Social Security Act which is classified to part B of this subchapter], or both.''

TEMPORARY SUSPENSION OF OASIS REQUIREMENT FOR COVERAGE OF DATA ON NON-MEDICARE AND NON-MEDICAID PATIENTS

"(a) IN GENERAL.—During the period described in subsection (b), the Secretary of Health and Human Services may not require, under section 4602(e) of the Balanced Budget Act of 1997 (Public Law 105–33; 111 Stat. 467) [set out as a note under this section] or otherwise under OASIS, a home health agency to gather or submit information that relates to an individual who is not eligible for benefits under either title XVIII or title XIX of the Social Security Act [this subchapter and subchapter XIX of this chapter] (such information in this section referred to as ‘non-medicare/medicaid OASIS information’).

"(b) PERIOD OF SUSPENSION.—The period described in this subsection—
"(1) begins on the date of the enactment of this Act [Dec. 8, 2003]; and
"(2) ends on the last day of the second month beginning after the date as of which the Secretary has published final regulations regarding the collection and use by the Centers for Medicare & Medicaid Services of non-medicare/medicaid OASIS information following the submission of the report required under subsection (c).

"(c) REPORT.—
"(1) STUDY.—The Secretary shall conduct a study on how non-medicare/medicaid OASIS information is and can be used by large home health agencies. Such study shall examine—
"(A) whether there are unique benefits from the analysis of such information that cannot be derived from other information available to, or collected by, such agencies; and
"(B) the value of collecting such information by small home health agencies compared to the administrative burden related to such collection.

In conducting the study the Secretary shall obtain recommendations from quality assessment experts in the use of such information and the necessity of small, as well as large, home health agencies collecting such information.

"(2) REPORT.—The Secretary shall submit to Congress a report on the study conducted under paragraph (1) by not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003].

"(d) CONSTRUCTION.—Nothing in this section shall be construed as preventing home health agencies from collecting non-medicare/medicaid OASIS information for their own use.''

MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES

"(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395ff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

"(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 8, 2003], the Commission shall submit to Congress a report on the study under subsection (a).''

SPECIAL RULE FOR PAYMENT FOR FISCAL YEAR 2001 BASED ON ADJUSTED PROSPECTIVE PAYMENT AMOUNTS

Pub. L. 106–554, §1(a)(6) [title V, §502(b)], Dec. 21, 2000, 114 Stat. 2763, 2768A–530, provided that:
"(1) IN GENERAL.—Notwithstanding the amendments made by subsection (a) [amending section 1395x of this title], for purposes of making payments under section 1895(b) of the Social Security Act (42 U.S.C. 1395ff(b)) for home health services furnished during fiscal year 2001, the Secretary of Health and Human Services shall—

"(A) with respect to episodes and visits ending on or after October 1, 2000, and before April 1, 2001, use the final standardized and budget neutral prospective payment amounts for 60-day episodes and standardized average per visit amounts for fiscal year 2001 as published by the Secretary in the Federal Register on July 3, 2000 (65 Fed. Reg. 41126–41214); and

"(B) with respect to episodes and visits ending on or after April 1, 2001, and before October 1, 2001, use such amounts increased by 2.2 percent.

"(2) NO EFFECT ON OTHER PAYMENTS OR DETERMINATIONS.—The Secretary shall not take the provisions of paragraph (1) into account for purposes of payments, determinations, or budget neutrality adjustments under section 1895 of the Social Security Act.

TEMPORARY TWO-MONTH PERIODIC INTERIM PAYMENT

Pub. L. 106–554, §1(a)(6) [title V, §503], Dec. 21, 2000, 114 Stat. 2763, 2768A–530, provided that:
"(a) IN GENERAL.—Notwithstanding the amendments made by section 4063(b) of BBA [Pub. L. 105–33, amending section 1395x of this title] (42 U.S.C. 1395ff note), in the case of a home health agency that was receiving periodic interim payments under section 1815(e)(2) of the Social Security Act (42 U.S.C. 1395g(e)(2)) as of September 30, 2000, and that is not described in subsection (b), the Secretary of Health and Human Services shall, as soon as practicable, make a single periodic interim payment to such agency in an amount equal to four times the last full fortnightly periodic interim payment made to such agency under the payment system in effect prior to the implementation of the prospective payment system under section 1895(b) of such Act (42 U.S.C. 1395ff(b)). Such amount of such periodic interim payment shall be included in the tentative settlement of the last cost report for the home health agency under the payment system in effect prior to the implementation of such prospective payment system, regardless of the ending date of such cost report.

"(b) EXCEPTIONS.—The Secretary shall not make an additional periodic interim payment under subsection (a) in the case of a home health agency (determined as of the day that such payment would otherwise be made) that—

"(1) notifies the Secretary that such agency does not want to receive such payment;

"(2) is not receiving payments pursuant to section 405.371 of title 42, Code of Federal Regulations;

"(3) is excluded from the medicare program under title XI of the Social Security Act [subchapter XI of this chapter];

"(4) no longer has a provider agreement under section 1866 of such Act (42 U.S.C. 1395cc);

"(5) is no longer in business; or

"(6) is subject to a court order providing for the withholding of medicare payments under title XVIII of such Act [this subchapter]."
TEMPORARY INCREASE FOR HOME HEALTH SERVICES
FURNISHED IN A RURAL AREA

Pub. L. 106–554, §1(a)(6) [title V, §508], Dec. 21, 2000, 114 Stat. 2763, 2763A–533, provided that:

"(a) MONTH INCREASE BEGINNING APRIL 1, 2001.—In the case of home health services furnished in a rural area (as defined in section 1866(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) on or after April 1, 2001, and before April 1, 2003, the Secretary of Health and Human Services shall increase the payment amount otherwise made under section 1866 of such Act (42 U.S.C. 1395x) for such services by 10 percent.

"(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a)."

CLARIFICATION OF APPLICATION OF TEMPORARY PAYMENT INCREASES FOR 2001

Pub. L. 106–554, §1(a)(6) [title V, §547(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–533, provided that:

"(1) TRANSITIONAL ALLOWANCE FOR FULL MARKET篮ASK (sic) INCREASE.—The payment increase provided under section 508(b)(1)(B) [set out as a note above] shall not apply to episodes and visits ending after fiscal year 2001 and shall not be taken into account in calculating the payment amounts applicable for subsequent episodes and visits.

"(2) TEMPORARY INCREASE FOR RURAL HOME HEALTH SERVICES.—The payment increase provided under section 508(a) [set out as a note above] for the period beginning on April 1, 2001, and ending on September 30, 2002, shall not apply to episodes and visits ending after such period, and shall not be taken into account in calculating the payment amounts applicable for episodes and visits occurring after such period."

ADJUSTMENT TO REFLECT ADMINISTRATIVE COSTS NOT INCLUDED IN THE INTERIM PAYMENT SYSTEM; GAO REPORT ON COSTS OF COMPLIANCE WITH OASIS DATA COLLECTION REQUIREMENTS


"(1) GENERAL.—In the case of a home health agency that furnishes home health services to a medicare beneficiary, for each such beneficiary to whom the agency furnishes such services during the agency's cost reporting period beginning in fiscal year 2000, the Secretary of Health and Human Services shall pay the agency, in addition to any amount of payment made under section 1861(v)(1)(L)(vi)(II) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(vi)(II)) for the beneficiary and only for such cost reporting period, an aggregate amount of $10 to defray costs incurred by the agency attributable to data collection and reporting requirements under the Outcome and Assessment Information Set (OASIS) required by reason of section 4602(e) of BBA (the Balanced Budget Act of 1997, Pub. L. 105–33) (42 U.S.C. 1395f(d) note).

"(2) PAYMENT SCHEDULE

"(A) MIDYEAR PAYMENT.—Not later than April 1, 2000, the Secretary shall pay to a home health agency an amount that the Secretary estimates to be 50 percent of the aggregate amount payable to the agency by reason of this subsection.

"(B) UPON SETTLED COST REPORT.—The Secretary shall pay the balance of amounts payable to an agency under this subsection on the date that the cost report submitted by the agency for the cost reporting period beginning in fiscal year 2000 is settled.

"(3) PAYMENT FROM TRUST FUNDS.—Payments under this subsection shall be made, in appropriate part as specified by the Secretary, from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund.

"(4) DEFINITIONS.—In this subsection:

"(A) HOME HEALTH AGENCY.—The term ‘home health agency’ has the meaning given that term under section 1861(o) of the Social Security Act (42 U.S.C. 1395x(o)).

"(B) HOME HEALTH SERVICES.—The term ‘home health services’ has the meaning given that term under section 1861(m) of such Act (42 U.S.C. 1395x(m)).

"(C) MEDICARE BENEFICIARY.—The term ‘medicare beneficiary’ means a beneficiary described in section 1861(v)(1)(L)(vi)(II) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(vi)(II)).

"(D) GAO REPORT ON COSTS OF COMPLIANCE WITH OASIS DATA COLLECTION REQUIREMENTS.—

"(1) REPORT TO CONGRESS.—

"(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [Nov. 29, 1999], the Comptroller General of the United States shall submit to Congress a report on the matters described in subparagraph (B) with respect to the data collection requirement of patients of such agencies under the Outcome and Assessment Information Set (OASIS) standard as part of the comprehensive assessment of patients.

"(B) MATTERS STUDIED.—For purposes of subparagraph (A), the matters described in this subparagraph include the following:

"(i) An assessment of the costs incurred by medicare home health agencies in complying with such data collection requirement.

"(ii) An analysis of the effect of such data collection requirement on the privacy interests of patients from whom data is collected.

"(C) AUDIT.—The Comptroller General shall conduct an independent audit of the costs described in subparagraph (B)(i). Not later than 180 days after receipt of the report under subparagraph (A), the Comptroller General shall submit to Congress a report describing the Comptroller General's findings with respect to such audit, and shall include comments on the report submitted to Congress by the Secretary of Health and Human Services under subparagraph (A).

"(2) DEFINITIONS.—In this subsection:

"(A) COMPREHENSIVE ASSESSMENT OF PATIENTS.—The term ‘comprehensive assessment of patients’ means the rule published by the Health Care Financing Administration that requires, as a condition of participation in the medicare program, a home health agency to provide a patient-specific comprehensive assessment that accurately reflects the patient’s current status and that incorporates the Outcome and Assessment Information Set (OASIS).

"(B) OUTCOME AND ASSESSMENT INFORMATION SET.—The term ‘Outcome and Assessment Information Set’ means the standard provided under the rule relating to data items that must be used in conducting a comprehensive assessment of patients.

REPORT TO CONGRESS ON NEED FOR REDUCTIONS

Pub. L. 106–113, div. B, §1000(a)(6) [title III, §302(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–360, as amended by Pub. L. 106–554, §1(a)(6) [title V, §501(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–539, provided that: ‘‘Not later than April 1, 2002, the Comptroller General of the United States shall submit to Congress a report analyzing the need for the 15 percent reduction under subsection (b)(3)(A)(ii) of such section [subsec. (b)(3)(A)(ii) of this section], or for any reduction, in the computation of the base payment amounts under the prospective payment system for home health services established under such section.’’

STUDY AND REPORT TO CONGRESS REGARDING EXEMPTION OF RURAL AGENCIES AND POPULATIONS FROM INCLUSION IN HOME HEALTH PROSPECTIVE PAYMENT SYSTEM

"(a) STUDY.—The Medicare Payment Advisory Commission (referred to in this section as ‘‘MedPAC’’) shall conduct a study to determine the feasibility and advisability of exempting home health services provided by a home health agency (or by others under arrangements with such agency) located in a rural area, or to an individual residing in a rural area, from payment under the prospective payment system for such services established by the Secretary of Health and Human Services in accordance with section 1895 of the Social Security Act (42 U.S.C. 1395ggg).

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Nov. 29, 1999], MedPAC shall submit a report to Congress on the study conducted under subsection (a), together with any recommendations for legislation that MedPAC determines to be appropriate as a result of such study.’’

CASE MIX SYSTEM DEVELOPMENT

Section 4602(d) of Pub. L. 105–33 provided that: ‘‘The Secretary of Health and Human Services shall expand research on a prospective payment system for home health agencies under the medicare program that ties prospective payments to a unit of service, including an intensive effort to develop a reliable case mix adjuster that explains a significant amount of the variances in costs.’’

CASE MIX SYSTEM; SUBMISSION OF DATA

Section 4602(e) of Pub. L. 105–33 provided that: ‘‘Effective for cost reporting periods beginning on or after October 1, 1997, the Secretary of Health and Human Services may require all home health agencies to submit additional information that the Secretary considers necessary for the development of a reliable case mix system.’’

PROSPECTIVE PAYMENT SYSTEM CONTINGENCY

Pub. L. 105–33, title IV, § 4603(e), Aug. 5, 1997, 111 Stat. 471, as amended by Pub. L. 105–277, div. J, title V, § 5101(c)(3), Oct. 21, 1998, 112 Stat. 2681–914, provided that if the Secretary of Health and Human Services did not establish and implement the prospective payment system for home health services described in subsec. (b) of this section for portions of cost reporting periods described in section 4603(d) of Pub. L. 105–33 (set out as a note above), for such portions the Secretary was to provide for a reduction by 15 percent in the cost limits and per beneficiary limits described in section 1395x(v)(1)(L) of this title, as those limits would otherwise have been in effect on Sept. 30, 2000, prior to repeal by Pub. L. 106–113, div. B, § 1000(a)(6) [title III, § 302(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A–359.

REPORTS TO CONGRESS REGARDING HOME HEALTH COST CONTAINMENT

Section 4616 of Pub. L. 105–33 provided that: ‘‘(a) ESTIMATE.—Not later than October 1, 1997, the Secretary of Health and Human Services shall submit to the Committees on Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report that includes an estimate of the outlays that will be made under parts A and B of title XVIII of the Social Security Act [parts A and B of this subchapter] for the provision of home health services during each of fiscal years 1998 through 2002.

(b) ANNUAL REPORT.—Not later than the end of each of years 1999 through 2002, the Secretary shall submit to such Committees a report that compares the actual outlays under such parts for such services during the fiscal year ending in the year, to the outlays estimated under subsection (a) for such fiscal year. If the Secretary finds that such actual outlays were greater than such estimated outlays for the fiscal year, the Secretary shall include in the report recommendations regarding beneficiary copayments for home health services provided under the medicare program or such other methods as will reduce the growth in outlays for home health services under the medicare program.’’

§ 1395ggg. Omitted

CODIFICATION


§ 1395hhh. Health care infrastructure improvement program

(a) Establishment

The Secretary shall establish a loan program that provides loans to qualifying hospitals for payment of the capital costs of projects described in subsection (d) of this section.

(b) Application

No loan may be provided under this section to a qualifying hospital except pursuant to an application that is submitted and approved in a time, manner, and form specified by the Secretary. A loan under this section shall be on such terms and conditions and meet such requirements as the Secretary determines appropriate.

(c) Selection criteria

(1) In general

The Secretary shall establish criteria for selecting among qualifying hospitals that apply for a loan under this section. Such criteria shall consider the extent to which the project for which loan is sought is nationally or regionally significant, in terms of expanding or improving the health care infrastructure of the United States or the region or in terms of the medical benefit that the project will have.

(2) Qualifying hospital defined

For purposes of this section, the term ‘‘qualifying hospital’’ means a hospital or an entity described in paragraph (3) that—

(A) is engaged in research in the causes, prevention, and treatment of cancer; and

(B) is designated as a cancer center for the National Cancer Institute or is designated by the State legislature as the official cancer institute of the State.

(3) Entity described

An entity described in this paragraph is an entity that—

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

(B) has at least 1 existing memorandum of understanding or affiliation agreement with a hospital located in the State in which the entity is located; and

(C) retains clinical outpatient treatment for cancer on site as well as lab research and...
education and outreach for cancer in the same facility.

(d) Projects

A project described in this subsection is a project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

(e) State and local permits

The provision of a loan under this section with respect to a project shall not—

(1) relieve any recipient of the loan of any obligation to obtain any required State or local permit or approval with respect to the project;

(2) limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project; or

(3) otherwise supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

(f) Forgiveness of indebtedness

The Secretary may forgive a loan provided to a qualifying hospital under this section under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a et seq.), except that

(1) the Secretary shall condition such forgiveness on the establishment by the hospital of—

(A) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

(B) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

(C)(i) unique research resources (such as population databases); or

(ii) an affiliation with an entity that has unique research resources.

(g) Funding

(1) In general

There are appropriated, out of amounts in the Treasury not otherwise appropriated, to carry out this section, $220,000,000, to remain available during the period beginning on July 1, 2004, and ending on September 30, 2008.

(2) Administrative costs

From funds made available under paragraph (1), the Secretary may use, for the administration of this section, not more than $2,000,000 for each of fiscal years 2004 through 2008.

(3) Availability

Amounts appropriated under this section shall be available for obligation on July 1, 2004.

(h) Report to Congress

Not later than 4 years after December 8, 2003, the Secretary shall submit to Congress a report on the projects for which loans are provided under this section and a recommendation as to whether the Congress should authorize the Secretary to continue loans under this section beyond fiscal year 2008.

(i) Limitation on review

There shall be no administrative or judicial review of any determination made by the Secretary under this section.


REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (c)(3)(A), is classified generally to Title 26, Internal Revenue Code.


AMENDMENTS


Subsec. (c)(2)(B). Pub. L. 109–13, §6045(a)(1)(B), inserted “legislature” after “designated by the State” and “and such designation by the State legislature occurred prior to December 8, 2003” before period at end.


Effect Date of 2005 Amendment


§1395iii. Medicare Improvement Fund

(a) Establishment

The Secretary shall establish under this subchapter a Medicare Improvement Fund (in this section referred to as the “Fund”) which shall be available to the Secretary to make improvements under the original medicare fee-for-service program under parts A and B for individuals entitled to, or enrolled for, benefits under part A or enrolled under part B including, but not limited to, an increase in the conversion factor under section 1395w–4(d) of this title to address, in whole or in part, any projected shortfall in the conversion factor for 2014 relative to the conversion factor for 2008 and adjustments to payments for items and services furnished by providers of services and suppliers under such original medicare fee-for-service program.

(b) Funding

(1) In general

There shall be available to the Fund, for expenditures from the Fund for services furnished during—

(A) fiscal year 2014, $30;

(B) fiscal year 2015, $275,000,000; and

(C) fiscal year 2020 and each subsequent fiscal year, the Secretary’s estimate, as of July 1 of the fiscal year, of the aggregate reduction in expenditures under this subchapter during the preceding fiscal year di-
correctly resulting from the reduction in payment amounts under sections 1395w–4(a)(7), 1395w–23(b)(4), 1395w–23(m)(4), and 1395ww(b)(3)(B)(ix) of this title.

(2) Payment from Trust Funds

The amount specified under paragraph (1) shall be available to the Fund, as expenditures are made from the Fund, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines appropriate.

(3) Funding limitation

Amounts in the Fund shall be available in advance of appropriations but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under paragraph (1). The Secretary may obligate funds from the Fund only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

(4) No effect on payments in subsequent years

In the case that expenditures from the Fund are applied to, or otherwise affect, a payment rate for an item or service under this subchapter for a year, the payment rate for such item or service shall be computed for a subsequent year as if such application or effect had never occurred.


REFERENCES IN TEXT

Parts A and B, referred to in subsec. (a), are classified to section 1395c et seq. and section 1395j et seq., respectively, of this title.

AMENDMENTS

2010—Subsec. (b)(1)(A). Pub. L. 111–118, §1011(b)(1)(A), substituted “$20,740,000,000” for “$22,290,000,000”. Subsec. (b)(1)(B), Pub. L. 111–118, §1011(b)(1)(B)–(3), added subpar. (B) and redesignated former subpar. (B) as (C).

2008—Subsec. (b)(1). Pub. L. 110–379 substituted “$2,290,000,000” for “$2,220,000,000”.

2009—Subsec. (b)(1). Pub. L. 111–118, §1011(b)(1)(A), substituted “$20,740,000,000” for “$22,290,000,000”.

(b) Eligible ACOs

(1) In general

Subject to the succeeding provisions of this subsection, as determined appropriate by the Secretary, the following groups of providers of services and suppliers which have established a mechanism for shared governance are eligible to participate as ACOs under the program under this section:

(A) ACO professionals in group practice arrangements.

(B) Networks of individual practices of ACO professionals.

(C) Partnerships or joint venture arrangements between hospitals and ACO professionals.

(D) Hospitals employing ACO professionals.

(E) Such other groups of providers of services and suppliers as the Secretary determines appropriate.

(2) Requirements

An ACO shall meet the following requirements:

(A) The ACO shall be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.

(B) The ACO shall enter into an agreement with the Secretary to participate in the program.

1 So in original. No par. (2) has been enacted.
The Secretary shall have a formal legal structure that would allow the organization to receive and distribute payments for shared savings under subsection (d)(2) to participating providers of services and suppliers.

The Secretary shall include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under subsection (c). At a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it under subsection (c) in order to be eligible to participate in the ACO program.

The Secretary shall provide the Secretary with such information regarding ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements under paragraph (3), and the determination of payments for shared savings under subsection (d)(2).

The ACO shall have in place a leadership and management structure that includes clinical and administrative systems.

The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.

The ACO shall demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.

(3) Quality and other reporting requirements

(A) In general

The Secretary shall determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of—

(i) clinical processes and outcomes;

(ii) patient and, where practicable, caregiver experience of care; and

(iii) utilization (such as rates of hospital admissions for ambulatory care sensitive conditions).

(B) Reporting requirements

An ACO shall submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. Such data may include care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up by ACO professionals, as the Secretary determines appropriate.

(C) Quality performance standards

The Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs. The Secretary shall seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care.

(D) Other reporting requirements

The Secretary may, as the Secretary determines appropriate, incorporate reporting requirements and incentive payments related to the physician quality reporting initiative (PQRI) under section 1395w-4 of this title, including such requirements and such payments related to electronic prescribing, electronic health records, and other similar initiatives under section 1395w-4 of this title, and may use alternative criteria than would otherwise apply under such section for determining whether to make such payments. The incentive payments described in the preceding sentence shall not be taken into consideration when calculating any payments otherwise made under subsection (d).

(4) No duplication in participation in shared savings programs

A provider of services or supplier that participates in any of the following shall not be eligible to participate in an ACO under this section:

(A) A model tested or expanded under section 1315a of this title that involves shared savings under this subchapter, or any other program or demonstration project that involves such shared savings.

(B) The independence at home medical practice pilot program under section 1385cc-5 of this title.

(c) Assignment of Medicare fee-for-service beneficiaries to ACOs

The Secretary shall determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this subchapter by an ACO professional described in subsection (h)(1)(A).

(d) Payments and treatment of savings

(1) Payments

(A) In general

Under the program, subject to paragraph (3), payments shall continue to be made to providers of services and suppliers participating in an ACO under the original Medicare fee-for-service program under parts A and B in the same manner as they would otherwise be made except that a participating ACO is eligible to receive payment for shared savings under paragraph (2) if—

(i) the ACO meets quality performance standards established by the Secretary under subsection (b)(3); and

(ii) the ACO meets the requirement under subparagraph (B)(i).

(B) Savings requirement and benchmark

(i) Determining savings

In each year of the agreement period, an ACO shall be eligible to receive payment for shared savings under paragraph (2) only if the estimated average per capita Medi-
care expenditures under the ACO for Medicare fee-for-service beneficiaries for parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under clause (ii). The Secretary shall determine the appropriate percent described in the preceding sentence to account for normal variation in expenditures under this subchapter, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.

(ii) Establish and update benchmark
The Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per-beneficiary expenditures for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate and updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary. Such benchmark shall be reset at the start of each agreement period.

(2) Payments for shared savings
Subject to performance with respect to the quality performance standards established by the Secretary under subsection (b)(3), if an ACO meets the requirements under paragraph (1), a percent (as determined appropriate by the Secretary) of the difference between such estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO may be paid to the ACO as shared savings and the remainder of such difference shall be retained by the program under this subchapter. The Secretary shall establish limits on the total amount of shared savings that may be paid to an ACO under this paragraph.

(3) Monitoring avoidance of at-risk patients
If the Secretary determines that an ACO has taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO the Secretary may impose an appropriate sanction on the ACO, including termination from the program.

(4) Termination
The Secretary may terminate an agreement with an ACO if it does not meet the quality performance standards established by the Secretary under subsection (b)(3).

(e) Administration
Chapter 35 of title 44 shall not apply to the program.

(f) Waiver authority
The Secretary may waive such requirements of sections 1320a–7a and 1320a–7b of this title and this subchapter as may be necessary to carry out the provisions of this section.

(g) Limitations on review
There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of—

(1) the specification of criteria under subsection (a)(1)(B);
(2) the assessment of the quality of care furnished by an ACO and the establishment of performance standards under subsection (b)(3);
(3) the assignment of Medicare fee-for-service beneficiaries to an ACO under subsection (c);
(4) the determination of whether an ACO is eligible for shared savings under subsection (d)(2) and the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO under subsection (d)(1)(B);
(5) the percent of shared savings specified by the Secretary under subsection (d)(2) and any limit on the total amount of shared savings established by the Secretary under such subsection; and
(6) the termination of an ACO under subsection (d)(4).

(h) Definitions
In this section:

(1) ACO professional
The term "ACO professional" means—

(A) a physician (as defined in section 1395x(r)(1) of this title); and
(B) a practitioner described in section 1395u(b)(18)(C)(i) of this title.

(2) Hospital
The term "hospital" means—

(A) a provider described in subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title).

(3) Medicare fee-for-service beneficiary
The term "Medicare fee-for-service beneficiary" means an individual who is enrolled in the original Medicare fee-for-service program under parts A and B and is not enrolled in an MA plan under part C, an eligible organization under section 1395mm of this title, or a PACE program under section 1395eee of this title.

(i) Option to use other payment models
(1) In general
If the Secretary determines appropriate, the Secretary may use any of the payment models described in paragraph (2) or (3) for making payments under the program rather than the payment model described in subsection (d).

(2) Partial capitation model
(A) In general
Subject to subparagraph (B), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model

Subject to paragraph (A), a model described in this paragraph is a partial capitation model in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model
model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary.

(B) No additional program expenditures
Payments to an ACO for items and services under this subchapter for beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented, as estimated by the Secretary.

(3) Other payment models
(A) In general
Subject to subparagraph (B), a model described in this paragraph is any payment model that the Secretary determines will improve the quality and efficiency of items and services furnished under this subchapter.

(B) No additional program expenditures
Subparagraph (B) of paragraph (2) shall apply to a payment model under subparagraph (A) in a similar manner as such subparagraph (B) applies to the payment model under paragraph (2).

(j) Involvement in private payer and other third party arrangements
The Secretary may give preference to ACOs who are participating in similar arrangements with other payers.

(k) Treatment of physician group practice demonstration
During the period beginning on March 23, 2010, and ending on the date the program is established, the Secretary may enter into an agreement with an ACO under the demonstration under section 1395cc–1 of this title, subject to rebasing and other modifications deemed appropriate by the Secretary.


References in Text
Parts A, B, and C, referred to in text, are classified to sections 1395c et seq., 1395j et seq., and 1395w–21 et seq., respectively, of this title.

Amendments
2010—Subsecs. (i) to (k). Pub. L. 111–148, added subsecs. (i) to (k).

§ 1395kkk. Independent Payment Advisory Board

(a) Establishment
There is established an independent board to be known as the “Independent Payment Advisory Board”.

(b) Purpose
It is the purpose of this section to, in accordance with the following provisions of this section, reduce the per capita rate of growth in Medicare spending—

(1) by requiring the Chief Actuary of the Centers for Medicare & Medicaid Services to determine in each year to which this section applies (in this section referred to as “a determination year”) the projected per capita growth rate under Medicare for the second year following the determination year (in this section referred to as “an implementation year”);

(2) if the projection for the implementation year exceeds the target growth rate for that year, by requiring the Board to develop and submit during the first year following the determination year (in this section referred to as “a proposal year”) a proposal containing recommendations to reduce the Medicare per capita growth rate to the extent required by this section; and

(3) by requiring the Secretary to implement such proposals unless Congress enacts legislation pursuant to this section.

(c) Board proposals
(1) Development
(A) In general
The Board shall develop detailed and specific proposals related to the Medicare program in accordance with the succeeding provisions of this section.

(B) Advisory reports
Beginning January 15, 2014, the Board may develop and submit to Congress advisory reports on matters related to the Medicare program, regardless of whether or not the Board submitted a proposal for such year. Such a report may, for years prior to 2020, include recommendations regarding improvements to payment systems for providers of services and suppliers who are not otherwise subject to the scope of the Board’s recommendations in a proposal under this section. Any advisory report submitted under this subparagraph shall be subject to the rules for congressional consideration under subsection (d). In any year (beginning with 2014) that the Board is not required to submit a proposal under this section, the Board shall submit to Congress an advisory report on matters related to the Medicare program.

(2) Proposals
(A) Requirements
Each proposal submitted under this section in a proposal year shall meet each of the following requirements:

(i) If the Chief Actuary of the Centers for Medicare & Medicaid Services has made a determination under paragraph (7)(A) in the determination year, the proposal shall include recommendations so that the proposal as a whole (after taking into account recommendations under clause (v)) will result in a net reduction in total Medicare program spending in the implementation year that is at least equal to the applicable savings target established under paragraph (7)(B) for such implementation year. In determining whether a proposal meets the requirement of the preceding sentence, reductions in Medicare program spending during the 3-month period immediately
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preceding the implementation year shall be counted to the extent that such reductions are a result of the implementation of recommendations contained in the proposal for a change in the payment rate for an item or service that was effective during such period pursuant to subsection (e)(2)(A).

(ii) The proposal shall not include any recommendation to ration health care, raise revenues or Medicare beneficiary premiums under section 1395f–2, 1395f–2a, or 1395w of this title, increase Medicare beneficiary cost-sharing (including deductibles, coinsurance, and copayments), or otherwise restrict benefits or modify eligibility criteria.

(iii) In the case of proposals submitted prior to December 31, 2018, the proposal shall not include any recommendation that would reduce payment rates for items and services furnished, prior to December 31, 2019, by providers of services (as defined in section 1395x(u) of this title) and suppliers (as defined in section 1395x(d) of this title) scheduled, pursuant to the amendments made by section 3401 of the Patient Protection and Affordable Care Act, to receive a reduction in the inflationary payment updates of such providers of services and suppliers in excess of a reduction due to productivity in a year in which such recommendations would take effect.

(iv) As appropriate, the proposal shall include recommendations to reduce Medicare payments under parts C and D, such as reductions in direct subsidy payments to Medicare Advantage and prescription drug plans specified under paragraph (1) and (2) of section 1395w–115(a) of this title that are related to administrative expenses (including profits) for basic coverage, denying high bids or removing high bids for prescription drug coverage from the calculation of the national average monthly bid amount under section 1395w–113(a)(4) of this title, and reductions in payments to Medicare Advantage plans under clauses (i) and (ii) of section 1395w–23(a)(1)(B) of this title that are related to administrative expenses (including profits) and performance bonuses for Medicare Advantage plans under section 1395w–23(a) of this title. Any such recommendations shall not affect the base beneficiary premium percentage specified under 1395w–113(a) of this title or the full premium subsidy under section 1395w–114(a) of this title.

(v) The proposal shall include recommendations with respect to administrative funding for the Secretary to carry out the recommendations contained in the proposal.

(vi) The proposal shall only include recommendations related to the Medicare program.

(vii) If the Chief Actuary of the Centers for Medicare & Medicaid Services has made a determination described in subsection (e)(3)(B)(i)(II) in the determination year, the proposal shall be designed to help reduce the growth rate described in paragraph (8) while maintaining or enhancing beneficiary access to quality care under this subchapter.

(B) Additional considerations

In developing and submitting each proposal under this section in a proposal year, the Board shall, to the extent feasible—

(i) give priority to recommendations that extend Medicare solvency;

(ii) include recommendations that—

(I) improve the health care delivery system and health outcomes, including by promoting integrated care, care coordination, prevention and wellness, and quality and efficiency improvement; and

(II) protect and improve Medicare beneficiaries’ access to necessary and evidence-based items and services, including in rural and frontier areas;

(iii) include recommendations that target reductions in Medicare program spending to sources of excess cost growth;

(iv) consider the effects on Medicare beneficiaries of changes in payments to providers of services (as defined in section 1395x(u) of this title) and suppliers (as defined in section 1395x(d) of this title);

(v) consider the effects of the recommendations on providers of services and suppliers with actual or projected negative cost margins or payment updates;

(vi) consider the unique needs of Medicare beneficiaries who are dually eligible for Medicare and the Medicaid program under subchapter XIX; and

(vii) take into account the data and findings contained in the annual reports under subsection (n) in order to develop proposals that can most effectively promote the delivery of efficient, high quality care to Medicare beneficiaries.

(C) No increase in total Medicare program spending

Each proposal submitted under this section shall be designed in such a manner that implementation of the recommendations contained in the proposal would not be expected to result, over the 10-year period starting with the implementation year, in any increase in the total amount of net Medicare program spending relative to the total amount of net Medicare program spending that would have occurred absent such implementation.

(D) Consultation with MEDPAC

The Board shall submit a draft copy of each proposal to be submitted under this section to the Medicare Payment Advisory Commission established under section 1395b–6 of this title for its review. The Board shall submit such draft copy by not later than September 1 of the determination year.
(E) Review and comment by the Secretary

The Board shall submit a draft copy of each proposal to be submitted to Congress under this section to the Secretary for the Secretary’s review and comment. The Board shall submit such draft copy by not later than September 1 of the determination year. Not later than March 1 of the submission year, the Secretary shall submit a report to Congress on the results of such review, unless the Secretary submits a proposal under paragraph (5)(A) in that year.

(F) Consultations

In carrying out its duties under this section, the Board shall engage in regular consultations with the Medicaid and CHIP Payment and Access Commission under section 1396 of this title.

(3) Submission of Board proposal to Congress and the President

(A) In general

(i) In general

Except as provided in clause (ii) and subsection (f)(3)(B), the Board shall submit a proposal under this section to Congress and the President on January 15 of each year (beginning with 2014).

(ii) Exception

The Board shall not submit a proposal under clause (i) in a proposal year if the year is—

(I) a year for which the Chief Actuary of the Centers for Medicare & Medicaid Services makes a determination in the determination year under paragraph (6)(A) that the growth rate described in clause (i) of such paragraph does not exceed the growth rate described in clause (ii) of such paragraph; or

(II) a year in which the Chief Actuary of the Centers for Medicare & Medicaid Services makes a determination in the determination year that the projected percentage increase (if any) for the medical care expenditure category of the Consumer Price Index for All Urban Consumers (all items; United States city average) for the implementation year is less than the projected percentage increase (if any) in the Consumer Price Index for All Urban Consumers (all items; United States city average) for such implementation year.

(iii) Start-up period

The Board may not submit a proposal under clause (i) prior to January 15, 2014.

(B) Required information

Each proposal submitted by the Board under subparagraph (A)(i) shall include—

(i) the recommendations described in paragraph (2)(A)(i);

(ii) an explanation of each recommendation contained in the proposal and the reasons for including such recommendation;

(iii) an actuarial opinion by the Chief Actuary of the Centers for Medicare & Medicaid Services certifying that the proposal meets the requirements of subparagraphs (A)(i) and (C) of paragraph (2);

(iv) a legislative proposal that implements the recommendations; and

(v) other information determined appropriate by the Board.

(4) Presidential submission to Congress

Upon receiving a proposal from the Secretary under paragraph (5), the President shall within 2 days submit such proposal to Congress.

(5) Contingent secretarial development of proposal

If, with respect to a proposal year, the Board is required, but fails, to submit a proposal to Congress and the President by the deadline applicable under paragraph (3)(A)(i), the Secretary shall develop a detailed and specific proposal that satisfies the requirements of subparagraphs (A) and (C) (and, to the extent feasible, subparagraph (B)) of paragraph (2) and contains the information required paragraph (3)(B)). By not later than January 25 of the year, the Secretary shall transmit—

(A) such proposal to the President; and

(B) a copy of such proposal to the Medicare Payment Advisory Commission for its review.

(6) Per capita growth rate projections by Chief Actuary

(A) In general

Subject to subsection (f)(3)(A), not later than April 30, 2013, and annually thereafter, the Chief Actuary of the Centers for Medicare & Medicaid Services shall determine in each such year whether—

(i) the projected Medicare per capita growth rate for the implementation year (as determined under subparagraph (B));

(ii) the projected Medicare per capita target growth rate for the implementation year (as determined under subparagraph (C)).

(B) Medicare per capita growth rate

(i) In general

For purposes of this section, the Medicare per capita growth rate for an implementation year shall be calculated as the projected 5-year average (ending with such year) of the growth in Medicare program spending (calculated as the sum of per capita spending under each of parts A, B, and D).

(ii) Requirement

The projection under clause (i) shall—

(I) to the extent that there is projected to be a negative update to the single conversion factor applicable to payments for physicians’ services under section 1395w-4(d) of this title furnished in the proposal year or the implementation year, assume that such update for such services is 0 percent rather than the negative percent that would otherwise apply; and

(II) take into account any delivery system reforms or other payment changes that have been enacted or published in
(C) Medicare per capita target growth rate

For purposes of this section, the Medicare per capita target growth rate for an implementation year shall be calculated as the projected 5-year average (ending with such year) percentage increase in—

(1) introduction

Aper capita target growth rate for an implementation year shall be calculated as the projected 5-year average (ending with such year) percentage increase in—

(ii) the applicable percent for the implementation year.

(C) Applicable percent

For purposes of subparagraph (B), the applicable percent for an implementation year is the lesser of—

(i) in the case of—

(I) implementation year 2015, 0.5 percent;

(ii) the total amount of projected Medicare program spending for the proposal year;

(ii) the projected excess for the implementation year (expressed as a percent) determined under subparagraph (A).

(8) Per capita rate of growth in national health expenditures

In each determination year (beginning in 2018), the Chief Actuary of the Centers for Medicare & Medicaid Services shall project the per capita rate of growth in national health expenditures for the implementation year. Such rate of growth for an implementation year shall be calculated as the projected 5-year average (ending with such year) percentage increase in national health care expenditures.

(d) Congressional consideration

(1) Introduction

(A) In general

On the day on which a proposal is submitted to the Board or the President to the House of Representatives and the Senate under subsection (c)(3)(A)(i) or subsection (c)(4), the legislative proposal (described in subsection (c)(3)(B)(iv)) contained in the proposal shall be introduced (by request) in the Senate by the majority leader of the Senate or by Members of the Senate designated by the majority leader of the Senate and shall be introduced (by request) in the House by the majority leader of the House or by Members of the House designated by the majority leader of the House.

(B) Not in session

If either House is not in session on the day on which such legislative proposal is submitted, the legislative proposal shall be introduced in that House, as provided in subparagraph (A), on the first day thereafter on which that House is in session.

(C) Any Member

If the legislative proposal is not introduced in either House within 5 days on which that House is in session after the day on which the legislative proposal is submitted, then any Member of that House may introduce the legislative proposal.

(D) Referral

The legislation introduced under this paragraph shall be referred by the Presiding Officers of the respective Houses to the Committee on Ways and Means and the Committee on Energy and Commerce in the Senate to the Committee on Finance of the Senate and to the Committee on Energy and Commerce of the House of Representatives.

(2) Committee consideration of proposal

(A) Reporting bill

Not later than April 1 of any proposal year in which a proposal is submitted by the Board or the President to Congress under this section, the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate may report the bill referred to the Committee under paragraph (1)(D) with committee amendments related to the Medicare program.

(B) Calculations

In determining whether a committee amendment meets the requirement of subparagraph (A), the reductions in Medicare program spending during the 3-month period immediately preceding the implementation year shall be counted to the extent that such reductions are a result of the implementation provisions in the committee amend-
ment for a change in the payment rate for an item or service that was effective during such period pursuant to such amendment.

(C) Committee jurisdiction

Notwithstanding rule XV of the Standing Rules of the Senate, a committee amendment described in subparagraph (A) may include matter not within the jurisdiction of the Committee on Finance if that matter is relevant to a proposal contained in the bill submitted under subsection (c)(3).

(D) Discharge

If, with respect to the House involved, the committee has not reported the bill by the date required by subparagraph (A), the committee shall be discharged from further consideration of the proposal.

(3) Limitation on changes to the Board recommendations

(A) In general

It shall not be in order in the Senate or the House of Representatives to consider any bill, resolution, or amendment, pursuant to this subsection or conference report thereon, that fails to satisfy the requirements of subparagraphs (A)(i) and (C) of subsection (c)(2).

(B) Limitation on changes to the Board recommendations in other legislation

It shall not be in order in the Senate or the House of Representatives to consider any bill, resolution, amendment, or conference report (other than pursuant to this section) that would repeal or otherwise change the recommendations of the Board if that change would fail to satisfy the requirements of subparagraphs (A)(i) and (C) of subsection (c)(2).

(C) Limitation on changes to this subsection

It shall not be in order in the Senate or the House of Representatives to consider any bill, resolution, amendment, or conference report that would repeal or otherwise change this subsection.

(D) Waiver

This paragraph may be waived or suspended in the Senate only by the affirmative vote of three-fifths of the Members, duly chosen and sworn.

(E) Appeals

An affirmative vote of three-fifths of the Members of the Senate, duly chosen and sworn, shall be required in the Senate to sustain an appeal of the ruling of the Chair on a point of order raised under this paragraph.

(4) Expedited procedure

(A) Consideration

A motion to proceed to the consideration of the bill in the Senate is not debatable.

(B) Amendment

(i) Time limitation

Debate in the Senate on any amendment to a bill under this section shall be limited to 1 hour, to be equally divided between, and controlled by, the mover and the manager of the bill, and debate on any amendment to an amendment, debatable motion, or appeal shall be limited to 30 minutes, to be equally divided between, and controlled by, the mover and the manager of the bill, except that in the event the manager of the bill is in favor of any such amendment, motion, or appeal, the time in opposition thereto shall be controlled by the minority leader or such leader’s designee.

(ii) Germane

No amendment that is not germane to the provisions of such bill shall be received.

(iii) Additional time

The leaders, or either of them, may, from the time under their control on the passage of the bill, allot additional time to any Senator during the consideration of any amendment, debatable motion, or appeal.

(iv) Amendment not in order

It shall not be in order to consider an amendment that would cause the bill to result in a net reduction in total Medicare program spending in the implementation year that is less than the applicable savings target established under subsection (c)(7)(B) for such implementation year.

(v) Waiver and appeals

This paragraph may be waived or suspended in the Senate only by the affirmative vote of three-fifths of the Members, duly chosen and sworn. An affirmative vote of three-fifths of the Members of the Senate, duly chosen and sworn, shall be required in the Senate to sustain an appeal of the ruling of the Chair on a point of order raised under this section.

(C) Consideration by the other House

(i) In general

The expedited procedures provided in this subsection for the consideration of a bill introduced pursuant to paragraph (1) shall not apply to such a bill that is received by one House from the other House if such a bill was not introduced in the receiving House.

(ii) Before passage

If a bill that is introduced pursuant to paragraph (1) is received by one House from the other House, after introduction but before disposition of such a bill in the receiving House, then the following shall apply:

(I) The receiving House shall consider the bill introduced in that House through all stages of consideration up to, but not including, passage.

(II) The question on passage shall be put on the bill of the other House as amended by the language of the receiving House.

(iii) After passage

If a bill introduced pursuant to paragraph (1) is received by one House from the
other House, after such a bill is passed by the receiving House, then the vote on passage of the bill that originates in the receiving House shall be considered to be the vote on passage of the bill received from the other House as amended by the language of the receiving House.

(iv) Disposition

Upon disposition of a bill introduced pursuant to paragraph (i) that is received by one House from the other House, it shall no longer be in order to consider the bill that originates in the receiving House.

(v) Limitation

Clauses (ii), (iii), and (iv) shall apply only to a bill received by one House from the other House if the bill—

(I) is related only to the program under this subchapter; and

(II) satisfies the requirements of subparagraphs (A)(i) and (C) of subsection (c)(2).

(D) Senate limits on debate

(i) In general

In the Senate, consideration of the bill and all debatable motions and appeals in connection therewith shall not exceed a total of 30 hours, which shall be divided equally between the majority and minority leaders or their designees.

(ii) Motion to further limit debate

A motion to further limit debate on the bill is in order and is not debatable.

(iii) Motion or appeal

Any debatable motion or appeal is debatable for not to exceed 1 hour, to be divided equally between those favoring and those opposing the motion or appeal.

(iv) Final disposition

After 30 hours of consideration, the Senate shall proceed, without any further debate on any question, to vote on the final disposition thereof to the exclusion of all motions not then pending before the Senate at that time or necessary to resolve the differences between the Houses and to the exclusion of all other motions, except a motion to table, or to reconsider and one quorum call on demand to establish the presence of a quorum (and motions required to establish a quorum) immediately before the final vote begins.

(E) Consideration in conference

(i) In general

Consideration in the Senate and the House of Representatives on the conference report or any messages between Houses shall be limited to 10 hours, equally divided and controlled by the majority and minority leaders of the Senate or their designees and the Speaker of the House of Representatives and the minority leader of the House of Representatives or their designees.

(ii) Time limitation

Debate in the Senate on any amendment under this subparagraph shall be limited to 1 hour, to be equally divided between, and controlled by, the mover and the manager of the bill, and debate on any amendment to an amendment, debatable motion, or appeal shall be limited to 30 minutes, to be equally divided between, and controlled by, the mover and the manager of the bill, except that in the event the manager of the bill is in favor of any such amendment, motion, or appeal, the time in opposition thereto shall be controlled by the minority leader or such leader’s designee.

(iii) Final disposition

After 10 hours of consideration, the Senate shall proceed, without any further debate on any question, to vote on the final disposition thereof to the exclusion of all motions not then pending before the Senate at that time or necessary to resolve the differences between the Houses and to the exclusion of all other motions, except a motion to table, or to reconsider and one quorum call on demand to establish the presence of a quorum (and motions required to establish a quorum) immediately before the final vote begins.

(iv) Limitation

Clauses (i) through (iii) shall only apply to a conference report, message or the amendments thereto if the conference report, message, or an amendment thereto—

(I) is related only to the program under this subchapter; and

(II) satisfies the requirements of subparagraphs (A)(i) and (C) of subsection (c)(2).

(F) Veto

If the President vetoes the bill debate on a veto message in the Senate under this subsection shall be 1 hour equally divided between the majority and minority leaders or their designees.

(5) Rules of the Senate and House of Representatives

This subsection and subsection (f)(2) are enacted by Congress—

(A) as an exercise of the rulemaking power of the Senate and the House of Representatives, respectively, and is deemed to be part of the rules of each House, respectively, but applicable only with respect to the procedure to be followed in that House in the case of bill under this section, and it supersedes other rules only to the extent that it is inconsistent with such rules; and

(B) with full recognition of the constitutional right of either House to change the rules (so far as they relate to the procedure of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

(e) Implementation of proposal

(1) In general

Notwithstanding any other provision of law, the Secretary shall, except as provided in

4 So in original. Probably should be preceded by "a".
paragraph (3), implement the recommendations contained in a proposal submitted by the Board or the President to Congress pursuant to this section on August 15 of the year in which the proposal is so submitted.

(2) Application

(A) In general

A recommendation described in paragraph (1) shall apply as follows:

(i) In the case of a recommendation that is a change in the payment rate for an item or service under Medicare in which payment rates change on a fiscal year basis (or a cost reporting period basis that relates to a fiscal year), on a calendar year basis (or a cost reporting period basis that relates to a calendar year), or on a rate year basis (or a cost reporting period basis that relates to a rate year), such recommendation shall apply to items and services furnished on the first of the first fiscal year, calendar year, or rate year (as the case may be) that begins after such August 15.

(ii) In the case of a recommendation relating to payments to plans under parts C and D, such recommendation shall apply to plan years beginning on the first day of the first calendar year that begins after such August 15.

(iii) In the case of any other recommendation, such recommendation shall be addressed in the regular regulatory process timeframe and shall apply as soon as practicable.

(B) Interim final rulemaking

The Secretary may use interim final rulemaking to implement any recommendation described in paragraph (1).

(3) Exceptions

(A) In general

The Secretary shall not implement the recommendations contained in a proposal submitted in a proposal year by the Board or the President to Congress pursuant to this section if—

(I) prior to August 15 of the proposal year, Federal legislation is enacted that includes the following provision: “This Act supercedes the recommendations of the Board contained in the proposal submitted, in the year which includes the date of enactment of this Act, to Congress under section 1899A of the Social Security Act.”; and

(ii) in the case of implementation year 2020 and subsequent implementation years, a joint resolution described in subsection (f)(1) is enacted not later than August 15, 2017.

(B) Limited additional exception

(i) In general

Subject to clause (ii), the Secretary shall not implement the recommendations contained in a proposal submitted by the Board or the President to Congress pursuant to this section in a proposal year (beginning with proposal year 2019) if—

(I) the Board was required to submit a proposal to Congress under this section in the year preceding the proposal year; and

(II) the chief Actuary of the Centers for Medicare & Medicaid Services makes a determination in the determination year that the growth rate described in subsection (c)(8) exceeds the growth rate described in subsection (c)(6)(A)(i).

(ii) Limited additional exception may not be applied in two consecutive years

This subparagraph shall not apply if the recommendations contained in a proposal submitted by the Board or the President to Congress pursuant to this section in the year preceding the proposal year were not required to be implemented by reason of this subparagraph.

(iii) No affect on requirement to submit proposals or for congressional consideration of proposals

Clause (i) and (ii) shall not affect—

(I) the requirement of the Board or the President to submit a proposal to Congress in a proposal year in accordance with the provisions of this section; or

(II) Congressional consideration of a legislative proposal (described in subsection (c)(3)(B)(iv)) contained such a proposal in accordance with subsection (d).

(4) No affect on authority to implement certain provisions

Nothing in paragraph (3) shall be construed to affect the authority of the Secretary to implement any recommendation contained in a proposal or advisory report under this section to the extent that the Secretary otherwise has the authority to implement such recommendation administratively.

(5) Limitation on review

There shall be no administrative or judicial review under section 1395f of this title, section 1395oo of this title, or otherwise of the implementation by the Secretary under this subsection of the recommendations contained in a proposal.

(f) Joint resolution required to discontinue the Board

(1) In general

For purposes of subsection (e)(3)(B), a joint resolution described in this paragraph means only a joint resolution—

(A) that is introduced in 2017 by not later than February 1 of such year;

(B) which does not have a preamble;

(C) the title of which is as follows: “Joint resolution approving the discontinuation of the process for consideration and automatic implementation of the annual proposal of the Independent Payment Advisory Board under section 1899A of the Social Security Act;” and

(D) the matter after the resolving clause of which is as follows: “That Congress approves

5So in original. Probably should be “Clauses”.
the discontinuation of the process for consideration and automatic implementation of the annual proposal of the Independent Payment Advisory Board under section 1899A of the Social Security Act. monument.

(2) Procedure

(A) Referral

A joint resolution described in paragraph (1) shall be referred to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate.

(B) Discharge

In the Senate, if the committee to which is referred a joint resolution described in paragraph (1) has not reported such joint resolution (or an identical joint resolution) at the end of 20 days after the joint resolution described in paragraph (1) is introduced, such committee may be discharged from further consideration of such joint resolution upon a petition supported in writing by 30 Members of the Senate, and such joint resolution shall be placed on the calendar.

(C) Consideration

(i) In general

In the Senate, when the committee to which a joint resolution is referred has reported, or when a committee is discharged (under subparagraph (C)) from further consideration of a joint resolution described in paragraph (1), it is at any time thereafter in order (even though a previous motion to the same effect has been disagreed to) for a motion to proceed to the consideration of the joint resolution to be made, and all points of order against the joint resolution (and against consideration of the joint resolution) are waived, except for points of order under the Congressional points of order, and appeals in connection therewith, shall be divided equally between the majority leader and the minority leader, or their designees. A motion further to postpone, or a motion to proceed to the consideration of other business, or a motion to recommence the joint resolution is not in order.

(ii) Debate limitation

In the Senate, consideration of the joint resolution, and on all debatable motions and appeals in connection therewith, shall be limited to not more than 10 hours, which shall be divided equally between the majority leader and the minority leader, or their designees. A motion further to limit debate is in order and not debatable. An amendment to, or a motion to postpone, or a motion to proceed to the consideration of other business, or a motion to recommence the joint resolution is not in order.

(iii) Passage

In the Senate, immediately following the conclusion of the debate on a joint resolu-
(ii) the Secretary, the Administrator of the Center for Medicare & Medicaid Services, and the Administrator of the Health Resources and Services Administration, all of whom shall serve ex officio as nonvoting members of the Board.

(B) Qualifications
(i) In general
The appointed membership of the Board shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic physicians, and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives.

(ii) Inclusion
The appointed membership of the Board shall include (but not be limited to) physicians and other health professionals, experts in the area of pharmaco-economics or prescription drug benefit programs, employers, third-party payers, individuals skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment. Such membership shall also include representatives of consumers and the elderly.

(iii) Majority nonproviders
Individuals who are directly involved in the provision or management of the delivery of items and services covered under this subchapter shall not constitute a majority of the appointed membership of the Board.

(C) Ethical disclosure
The President shall establish a system for public disclosure by appointed members of the Board of financial and other potential conflicts of interest relating to such members. Appointed members of the Board shall be treated as officers in the executive branch for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).

(D) Conflicts of interest
No individual may serve as an appointed member if that individual engages in any other business, vocation, or employment.

(E) Consultation with Congress
In selecting individuals for nominations for appointments to the Board, the President shall consult with—

(i) the majority leader of the Senate concerning the appointment of 3 members;

(ii) the Speaker of the House of Representatives concerning the appointment of 3 members;

(iii) the minority leader of the House of Representatives concerning the appointment of 3 members.

(iv) the minority leader of the Senate concerning the appointment of 3 members.

(2) Term of office
Each appointed member shall hold office for a term of 6 years except that—

(A) a member may not serve more than 2 full consecutive terms (but may be reappointed to 2 full consecutive terms after being appointed to fill a vacancy on the Board);

(B) a member appointed to fill a vacancy occurring prior to the expiration of the term for which that member's predecessor was appointed shall be appointed for the remainder of such term;

(C) a member may continue to serve after the expiration of the member's term until a successor has taken office; and

(D) of the members first appointed under this section, 5 shall be appointed for a term of 1 year, 5 shall be appointed for a term of 3 years, and 5 shall be appointed for a term of 6 years, the term of each to be designated by the President at the time of nomination.

(3) Chairperson
(A) In general
The Chairperson shall be appointed by the President, by and with the advice and consent of the Senate, from among the members of the Board.

(B) Duties
The Chairperson shall be the principal executive officer of the Board, and shall exercise all of the executive and administrative functions of the Board, including functions of the Board with respect to—

(i) the appointment and supervision of personnel employed by the Board;

(ii) the distribution of business among personnel appointed and supervised by the Chairperson and among administrative units of the Board; and

(iii) the use and expenditure of funds.

(C) Governance
In carrying out any of the functions under subparagraph (B), the Chairperson shall be governed by the general policies established by the Board and by the decisions, findings, and determinations the Board shall by law be authorized to make.

(D) Requests for appropriations
Requests or estimates for regular, supplemental, or deficiency appropriations on behalf of the Board may not be submitted by the Chairperson without the prior approval of a majority vote of the Board.

(4) Removal
Any appointed member may be removed by the President for neglect of duty or malfeasance in office, but for no other cause.

(h) Vacancies; quorum; seal; Vice Chairperson; voting on reports
(1) Vacancies
No vacancy on the Board shall impair the right of the remaining members to exercise all the powers of the Board.
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(2) Quorum
A majority of the appointed members of the Board shall constitute a quorum for the transation of business, but a lesser number of members may hold hearings.

(3) Seal
The Board shall have an official seal, of which judicial notice shall be taken.

(4) Vice Chairperson
The Board shall annually elect a Vice Chairperson to act in the absence or disability of the Chairperson or in case of a vacancy in the office of the Chairperson.

(5) Voting on proposals
Any proposal of the Board must be approved by the majority of appointed members present.

(i) Powers of the Board
(1) Hearings
The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this section.

(2) Authority to inform research priorities for data collection
The Board may advise the Secretary on priorities for health services research, particularly as such priorities pertain to necessary changes and issues regarding payment reforms under Medicare.

(3) Obtaining official data
The Board may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Chairperson, the head of that department or agency shall furnish that information to the Board on an agreed upon schedule.

(4) Postal services
The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(5) Gifts
The Board may accept, use, and dispose of gifts or donations of services or property.

(6) Offices
The Board shall maintain a principal office and such field offices as it determines necessary, and may meet and exercise any of its powers at any other place.

(j) Personnel matters
(1) Compensation of members and Chairperson
Each appointed member, other than the Chairperson, shall be compensated at a rate equal to the annual rate of basic pay prescribed for level III of the Executive Schedule under section 5315 of title 5. The Chairperson shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level II of the Executive Schedule under section 5315 of title 5.

(2) Travel expenses
The appointed members shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5 while away from their homes or regular places of business in the performance of services for the Board.

(3) Staff
(A) In general
The Chairperson may, without regard to the civil service laws and regulations, appoint and terminate an executive director and such other additional personnel as may be necessary to enable the Board to perform its duties. The employment of an executive director shall be subject to confirmation by the Board.

(B) Compensation
The Chairperson may fix the compensation of the executive director and other personnel without regard to chapter 51 and subchapter III of chapter 53 of title 5 relating to classification of positions and General Schedule pay rates, except that the rate of pay for the executive director and other personnel may not exceed the rate payable for level V of the Executive Schedule under section 5316 of such title.

(4) Detail of Government employees
Any Federal Government employee may be detailed to the Board without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

(5) Procurement of temporary and intermittent services
The Chairperson may procure temporary and intermittent services under section 3109(b) of title 5 at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

(k) Consumer advisory council
(1) In general
There is established a consumer advisory council to advise the Board on the impact of payment policies under this subchapter on consumers.

(2) Membership
(A) Number and appointment
The consumer advisory council shall be composed of 10 consumer representatives appointed by the Comptroller General of the United States, 1 from among each of the 10 regions established by the Secretary as of March 23, 2010.

(B) Qualifications
The membership of the council shall represent the interests of consumers and particular communities.

(3) Duties
The consumer advisory council shall, subject to the call of the Board, meet not less frequently than 2 times each year in the District of Columbia.

(4) Open meetings
Meetings of the consumer advisory council shall be open to the public.
(5) Election of officers
Members of the consumer advisory council shall elect their own officers.

(6) Application of FACA
The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the consumer advisory council except that section 14 of such Act shall not apply.

(l) Definitions
In this section:
(1) Board; Chairperson; Member
The terms “Board”, “Chairperson”, and “Member” mean the Independent Payment Advisory Board established under subsection (a) and the Chairperson and any Member thereof, respectively.

(2) Medicare
The term “Medicare” means the program established under this subchapter, including parts A, B, C, and D.

(3) Medicare beneficiary
The term “Medicare beneficiary” means an individual who is entitled to, or enrolled for, benefits under part A or enrolled for benefits under part B.

(4) Medicare program spending
The term “Medicare program spending” means program spending under parts A, B, and D net of premiums.

(m) Funding
(1) In general
There are appropriated to the Board to carry out its duties and functions—
(A) for fiscal year 2012, $15,000,000; and
(B) for each subsequent fiscal year, the amount appropriated under this paragraph for the previous fiscal year increased by the annual percentage increase in the Consumer Price Index for All Urban Consumers (all items; United States city average) as of June of the previous fiscal year.

(2) From trust funds
Sixty percent of amounts appropriated under paragraph (1), the Board shall coordinate such recommendations with recommendations contained in proposals and advisory reports produced by the Board under subsection (c).

(n) Annual public report
(1) In general
The Board shall produce a public report containing standardized information on system-wide health care costs, patient access to care, utilization, and quality-of-care that allows for comparison by region, types of services, types of providers, and both private payers and the program under this subchapter.

(2) Requirements
Each report produced pursuant to paragraph (1) shall include information with respect to the following areas:
(A) The quality and costs of care for the population at the most local level determined practical by the Board (with quality and costs compared to national benchmarks and reflecting rates of change, taking into account quality measures described in section 1395aaa(b)(7)(B) of this title).
(B) Beneficiary and consumer access to care, patient and caregiver experience of care, and the cost-sharing or out-of-pocket burden on patients.
(C) Epidemiological shifts and demographic changes.
(D) The proliferation, effectiveness, and utilization of health care technologies, including variation in provider practice patterns and costs.
(E) Any other areas that the Board determines affect overall spending and quality of care in the private sector.

(o) Advisory recommendations for non-Federal health care programs
(1) In general
Not later than January 15, 2015, and at least once every two years thereafter, the Board shall submit to Congress and the President recommendations to slow the growth in national health expenditures (excluding expenditures under this subchapter and in other Federal health care programs) while preserving or enhancing quality of care, such as recommendations—
(A) that the Secretary or other Federal agencies can implement administratively;
(B) that may require legislation to be enacted by Congress in order to be implemented;
(C) that may require legislation to be enacted by State or local governments in order to be implemented;
(D) that private sector entities can voluntarily implement; and
(E) with respect to other areas determined appropriate by the Board.

(2) Coordination
In making recommendations under paragraph (1), the Board shall coordinate such recommendations with recommendations contained in proposals and advisory reports produced by the Board under subsection (c).

(3) Available to public
The Board shall make recommendations submitted to Congress and the President under this subsection available to the public.

References in Text

The Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the consumer advisory council except that section 14 of such Act shall not apply.

Members of the consumer advisory council shall elect their own officers.

The terms “Board”, “Chairperson”, and “Member” mean the Independent Payment Advisory Board established under subsection (a) and the Chairperson and any Member thereof, respectively.

The term “Medicare” means the program established under this subchapter, including parts A, B, C, and D.

The term “Medicare beneficiary” means an individual who is entitled to, or enrolled for, benefits under part A or enrolled for benefits under part B.

The term “Medicare program spending” means program spending under parts A, B, and D net of premiums.

There are appropriated to the Board to carry out its duties and functions—
(A) for fiscal year 2012, $15,000,000; and
(B) for each subsequent fiscal year, the amount appropriated under this paragraph for the previous fiscal year increased by the annual percentage increase in the Consumer Price Index for All Urban Consumers (all items; United States city average) as of June of the previous fiscal year.

Sixty percent of amounts appropriated under paragraph (1), the Board shall coordinate such recommendations with recommendations contained in proposals and advisory reports produced by the Board under subsection (c).

The Board shall produce a public report containing standardized information on system-wide health care costs, patient access to care, utilization, and quality-of-care that allows for comparison by region, types of services, types of providers, and both private payers and the program under this subchapter.

Each report produced pursuant to paragraph (1) shall include information with respect to the following areas:
(A) The quality and costs of care for the population at the most local level determined practical by the Board (with quality and costs compared to national benchmarks and reflecting rates of change, taking into account quality measures described in section 1395aaa(b)(7)(B) of this title).
(B) Beneficiary and consumer access to care, patient and caregiver experience of care, and the cost-sharing or out-of-pocket burden on patients.
(C) Epidemiological shifts and demographic changes.
(D) The proliferation, effectiveness, and utilization of health care technologies, including variation in provider practice patterns and costs.
(E) Any other areas that the Board determines affect overall spending and quality of care in the private sector.

Not later than January 15, 2015, and at least once every two years thereafter, the Board shall submit to Congress and the President recommendations to slow the growth in national health expenditures (excluding expenditures under this subchapter and in other Federal health care programs) while preserving or enhancing quality of care, such as recommendations—
(A) that the Secretary or other Federal agencies can implement administratively;
(B) that may require legislation to be enacted by Congress in order to be implemented;
(C) that may require legislation to be enacted by State or local governments in order to be implemented;
(D) that private sector entities can voluntarily implement; and
(E) with respect to other areas determined appropriate by the Board.

In making recommendations under paragraph (1), the Board shall coordinate such recommendations with recommendations contained in proposals and advisory reports produced by the Board under subsection (c).

The Board shall make recommendations submitted to Congress and the President under this subsection available to the public.


Subsec. (e)(3). Pub. L. 111–148, §10320(a)(3)(B), substituted “Exceptions” for “Exception” in par. heading, designated existing provisions as subpars. (A) and (B) as cls. (i) and (ii), respectively, of subpar. (A) and realigned margins, and added subpar. (B).

Subsec. (f)(3)(B). Pub. L. 111–148, §10320(a)(4), substituted “‘advisor reports, or advisory recommendations’” for “or advisory reports to Congress” and inserted “‘or produce the public report under subsection (n)’ after “this section’.

Subsecs. (n) and (o). Pub. L. 111–148, §10320(a)(5), added subsecs. (n)(1) and (o).

§ 1395kkk–1. GAO study and report on determination and implementation of payment and coverage policies under the Medicare program

(1) Initial study and report

(A) Study

The Comptroller General of the United States (in this section referred to as the “Comptroller General”) shall conduct a study on changes to payment policies, methodologies, and rates and coverage policies and methodologies under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] as a result of the recommendations contained in the proposals made by the Independent Payment Advisory Board under section 1899A of such Act [42 U.S.C. 1395kkk] (as added by subsection (a)), including an analysis of the effect of such recommendations on—

(i) Medicare beneficiary access to providers and items and services;

(ii) the affordability of Medicare premiums and cost-sharing (including deductibles, coinsurance, and copayments);

(iii) the potential impact of changes on other government or private-sector purchasers and payers of care; and

(iv) quality of patient care, including patient experience, outcomes, and other measures of care.

1 See References in Text note below.
(B) Report
Not later than July 1, 2015, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(2) Subsequent studies and reports
The Comptroller General shall periodically conduct such additional studies and submit reports to Congress on changes to Medicare payments policies, methodologies, and rates and coverage policies and methodologies as the Comptroller General determines appropriate, in consultation with the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate.


REFERENCES IN TEXT
The Social Security Act, referred to in par. (1)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see section 1395kkk of this title and Tables.

(C) by not later than March 15 of each year (beginning with 2010), submit a report to Congress containing the results of such reviews and MACPAC’s recommendations concerning such policies; and

(D) by not later than June 15 of each year (beginning with 2010), submit a report to Congress containing an examination of issues affecting Medicaid and CHIP, including the implications of changes in health care delivery in the United States and in the market for health care services on such programs.

(2) Specific topics to be reviewed
Specifically, MACPAC shall review and assess the following:

(A) Medicaid and CHIP payment policies
Payment policies under Medicaid and CHIP, including—

(i) the factors affecting expenditures for the efficient provision of items and services in different sectors, including the process for updating payments to medical, dental, and health professionals, hospitals, residential and long-term care providers, providers of home and community based services, Federally-qualified health centers and rural health clinics, managed care entities, and providers of other covered items and services;

(ii) payment methodologies; and

(iii) the relationship of such factors and methodologies to access and quality of care for Medicaid and CHIP beneficiaries (including how such factors and methodologies enable such beneficiaries to obtain the services for which they are eligible, affect provider supply, and affect providers that serve a disproportionate share of low-income and other vulnerable populations).

(B) Eligibility policies
Medicaid and CHIP eligibility policies, including a determination of the degree to which Federal and State policies provide health care coverage to needy populations.

(C) Enrollment and retention processes
Medicaid and CHIP enrollment and retention processes, including a determination of the degree to which Federal and State policies encourage the enrollment of individuals who are eligible for such programs and screen out individuals who are ineligible, while minimizing the share of program expenses devoted to such processes.

(D) Coverage policies
Medicaid and CHIP benefit and coverage policies, including a determination of the degree to which Federal and State policies provide access to the services enrollees require to improve and maintain their health and functional status.

(E) Quality of care
Medicaid and CHIP policies as they relate to the quality of care provided under those programs, including an examination of the degree to which Federal and State policies achieve their stated goals and interact with similar goals established by other purchasers of health care services.